UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) April 22, 2004

ALIGN TECHNOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

0-32259 (Commission File Number) 94-3267295 (I.R.S. Employer Identification No.)

881 Martin Avenue, Santa Clara, California (Address of principal executive offices) 95050 (Zip Code)

Registrant's telephone number, including area code (408) 470-1000

Not applicable (Former name or former address, if changed since last report)

ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS

Item 12)

(c) Exhibits.

Poscription

99.1 Transcript of Conference Call conducted by Align Technology, Inc. on April 22, 2004 (furnished and not filed herewith solely pursuant to

ITEM 12. RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On April 22, 2004, Align Technology, Inc. ("Align") held a conference call to discuss its financial results for its first quarter ended March 31, 2004. A transcript of the conference call is furnished as Exhibit 99.1 to this Form 8-K.

The information contained in this Item 12 and in Exhibit 99.1 shall not be deemed "filed" for the purposes of Section 18 of the Exchange Ac or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any filing of Align, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference to such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: April 28, 2004 ALIGN TECHNOLOGY, INC.

By /s/ ELDON M. BULLINGTON

Eldon M. Bullington Vice President of Finance and Chief Financial Officer

INDEX TO EXHIBITS

Exhibit No. Description

99.1 Transcript of Conference Call conducted by Align Technology, Inc. on April 22, 2004 (furnished and not filed herewith solely pursuant to Item 12)

FORWARD LOOKING STATEMENTS

This conference call transcript contains forward-looking statements relating to the expectations of Align Technology, Inc. ("Align") about future events or future results, such as statements relating to: the continuing increase in orthodontist and GP dentist channel revenue and cases, the expected increase in the number of clinical education events, Align's anticipated expansion of market reach and penetration, the future expansion of the GP sales force, the expected continued improvements in flexibility, scalability and gross margin, the estimated size of Align's market opportunity, the projected financial metrics for the second quarter and the full fiscal year 2004, anticipated competition and the expected benefits from increased sales and marketing expenditures. Any forward-looking statements contained in this conference call transcript are based upon information available to Align as of the date hereof. 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 include, but are not limited to, risks relating to Align's limited operating history, customer demand for Invisalign, acceptance of Invisalign by consumers and dental professionals, competition from manufacturers of traditional braces, Align's third party manufacturing processes and personnel, foreign operational, political and other risks relating to Align's international manufacturing operations, Align's history of losses and negative operating cash flows, Align's ability to increase its revenue significantly while controlling expenses, Align's ability to protect its intellectual property rights and potential intellectual property or product liability claims or litigation. These and other risks are detailed from time to time in Align's periodic report filed with the Securities and Exchange Commission on Mar

PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by and welcome to the Align Technology first quarter 2004 conference call. During the presentation, all participants will be in a listen-only mode. Afterwards, we'll conduct a question and answer session. At that time, if you have a question, please press the one followed by the four on your telephone. As a reminder, this conference is being recorded, Thursday, April 22, 2004. I would now like to turn the conference over to Barbara Domingo, Director of Investor Relations. Please go ahead.

Barbara Domingo - Align Technology-Investor Relation

Thanks, and welcome to everyone on the line. If you haven't received a copy of our press release, please go to the Investor Relations page on our Web site at www.aligntech.com. Before we start the call today, I would 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 or its future results. 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 statement. Factors that might cause such a difference include, but are not limited to risks that are detailed from time to time in Align's periodic reports filed with the Securities and Exchange Commission, including, but not limited to, its Annual Report on Form 10-K for the fiscal year ended December 31, 2003, which was filed with the Securities and Exchange Commission on March 9, 2004, 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, which in the past, we referred to as pro forma financial measures. Most of these items together with the corresponding GAAP numbers and a reconciliation to the comparable GAAP financial measures when practicable are contained in today's financial results press release, which we have posted on our web site at www.aligntech.com, under corporate information, investor relations, earnings press releases, and refers to the Securities and Exchange Commission on Form 8-K. We encourage listeners to review these items. Additionally, we have posted a nine-quarter GAAP and non-GAAP revenue model on our web site at www.aligntech.com under corporate information, investor relations, financial history. Please refer to both of these downloadable Excel spreadsheets for more detailed line item information. With that said, I'd like to introduce Align Technologies' President and CEO Tom Prescott, Tom?

Thomas M Prescott - Align Technology—President, CEO

Thank you Barbara. And welcome to our shareholders and friends who are listening on the phone today and through our web site. We have gotten off to a very good start in 2004. Eldon will go more deeply into the financials in just a few minutes, but let me start with some top and bottom line highlights. We reported \$39.2m in revenues for the first quarter of 2004. This is a sequential increase of 7.4% over the fourth quarter and an increase of 70.8% over the same quarter last year. We also reported our second GAAP profitable quarter at a penny of EPS. Net profit was \$557,000. Let me first take you to some key operating metrics and follow up with some statements about our strategies and key priorities. On the revenue side, both the orthodontist and GP dentist channel revenues and cases continue to increase. We saw a sequential increase in the ortho channel of 5.2% to \$21.5m. GP revenues sequentially increased 18.1% to \$12.6m. Overall, 55% of total revenues came from US orthodontists. During the quarter, we received orders for approximately 23,700 net new cases. This was an average of 376 cases per business day, and increase of 9% from the previous quarter. We shipped over 22,000 cases worldwide to customers this quarter and an increase of 8% over the previous quarter. Finally, I would to like share some case volume and channel statistics with you.

Approximately 7,700 doctors worldwide submitted cases during the first quarter, compared with 7,300 last quarter. The number of orthodontist submitting cases went up slightly to almost 3,800. 3,950 GP dentist submitted cases compared with 3,550. That's 3,950 GP's submitting versus 3,550 last quarter. Additionally, we

trained and certified over 700 new GP's in the US during the first quarter, bringing our base of certified GP's in North America to 10,400. And we've done a solid job of having doctors initiating Invisalign into their practices and return for additional case starts. Just over 82% of our North American clinicians and 80% of our certified docs worldwide have submitted more than one case. Let me turn now to some key activities and accomplishments in the first quarter. To start with, the first quarter has been a bit slower in terms of key events such as training, seminars and conferences for Align. While we did host a number of clinical education events, we expect to increase that significantly in the quarters to come. One addition we made in the first quarter was to launch a new advanced Invisalign Provider Workshop or IPW. The IPW-II Seminar is an advanced workshop for orthodontists. It's more clinically intensive and trains orthodontists on cases such as extraction and surgery. This seminar is for highly experienced docs who we believe will extend the applicability of the product by submitting cases with a higher degree of difficulty thus expanding our market reach and penetration.

We also negotiated a marketing partnership with CareCredit. CareCredit is one of the leading third-party financing organizations that offer flexible payment options to patients. We assisted in negotiating preferred discount rates for the doctors using CareCredit to finance Invisalign cases for their patients. This enables them to capture the entire patient fee upfront from CareCredit at a lower merchant fee while their patients have a variety of payment options to choose from. We understand from our doctors that the most popular product has been the 12-month no-interest loan. For Align, we believe this will help doctors expand their practices because they are able to charge a lower down-payment, avoid collection hassles and enable patients who are reluctant to enter treatment because of cost realize their dreams of having straight teeth the Invisalign way.

As part of our additional efforts to increase our presence in the North American GP market, we continue to expand our GP sales force. This expansion brings our overall domestic field organization to approximately 75 people. On the manufacturing side, we continued our automation improvements with the FlexLink material handling system. This has proved to be a significant enhancement in our aligner fabrication process. As we continue integrating FlexLink and other related technology into our manufacturing processes, we expect continued improvements in flexibility, scalability, and gross margin.

Moving forward in 2004, we'll continue to invest in programs that will insure robust operating platform and create leverage from the growth in cases we expect to continue. As developments occur, we'll spend time talking about them with you. Right now we're in the beginning stages of implementation, and it will be some time before we see quantitative results from that hard work.

We still have a lot of work to do. Our product Invisalign has an incredible market opportunity and we have a ways to go to ensure that we have the most predictable, reliable, customer-friendly solution possible, which will compel our customers to continue prescribing this treatment.

Let me just step back for a second. We have a number of new shareholders listening to the call today who may not fully understand our market opportunity. In the US alone, and I'll just start there, we believe there are around 2m people who have orthodontic treatment every year, and this is a conservative number. We've seen estimates as high as 2.5m or 3m. Subtracting from that 2m the children with immature dentition along with highly complex cases and we're looking at a market opportunity of about 800,000 new case starts. Last year, we sold 44,400 cases into the orthodontic offices --- into the channel where there is an opportunity today to treat 800,000 patients. That's barely 6% of our existing conservative market opportunity. That's just a start. Look beyond this existing opportunity to the GP dentist market and the 100m plus people that see their dentist regularly. I won't go into this market size discussion in any more detail, however, it's well addressed in all of our presentations on the web and is also explained in our annual report. The point is—there is still a big market out there that we have barely tapped. It's up to us to find a way to best increase our market penetration.

Before Eldon dives into the financials, I'd like to make some comments about our financial presentation of results. We have a clear path in order to achieving a true GAAP profit. We believe we're operating in a prudent manner so that we can deliver the greatest value to our shareholder. In the past, we've always presented non-GAAP results, which excludes stock-based compensation and restructuring. We'll start to move away from that presentation as stock-based compensation diminishes on the anniversary of our IPO in 2005. Remember, many public companies must reconcile the difference between the fair market value of options granted, before the IPO, and the grant price, and amortize that over the vesting period of options. For Align, the amortization period concludes on the four-year anniversary of the IPO, which will be in January 2005. I expect that during future earnings calls, we will provide more emphasis on GAAP financials along with the non-GAAP bottom line. I wanted to let you know this in order to get you ready for that event and structure your models accordingly. With that said, I will now turn the call over to Eldon Bullington, our CFO. After Eldon goes through our financials and our guidance for the second quarter of 2004 along with the full-year 2004, we will take some questions. Eldon?

Eldon M. Bullington - Align Technology—Vice President, Finance and CFO

Thanks Tom, and good morning to everyone on the call. As a quick reminder, our first quarter press release and 8-K filing of the same document are available on our Web site. As Tom mentioned, we look to start placing more emphasis on our GAAP financial presentation on future calls. For now, I'll give you the GAAP numbers, stock-based compensation, and then the math required to

arrive at the non-GAAP financials. We also want to make sure that you understand that the comparisons to previous guidance we've given, as much of that has been guidance on a non-GAAP basis. Our non-GAAP financial table, and reconciliation of GAAP to non-GAAP financials is still included in our press release. Additionally, we will continue to provide historical GAAP and non-GAAP financial tables on our Investor Relations web site under financial history. Let me move on now to our financials.

First, Q1 revenues as Tom mentioned were \$39.2m, up 7.4% from last quarter, and 70.8% from the same period a year-ago.

First quarter revenues by segment were \$21.5m for US ortho, \$12.6m for US GP, and \$3.5m for international. These channels represent 55%, 32%, and 9% of revenues respectively. Worldwide training and other revenues were \$1.5m.

GAAP gross profit for the first quarter of 2004 was \$25.8m, or 65.8% of revenue compared to \$23.6m, or 64.6% of revenues last quarter. This also compares to a gross profit of \$11m, or 48.1% of revenues for the first quarter of 2003. Included in cost of revenues for Q1 was approximately \$400,000 of stock-based compensation. To arrive at non-GAAP gross profit and margins, we add back the \$400,000 of stock-based comp. Non-GAAP gross profit for the first quarter was \$26.2m, or 66.9% of revenue. The increase in gross margin which was higher than our expectations is primarily attributable to slightly higher ASPs, or Average Selling Prices, and continued manufacturing process efficiencies in both our treatment operations facility in Costa Rica, and the aligner fabrication process. As Tom mentioned, we introduced additional automation enabling more efficient handling of aligners through the fabrication stages of our manufacturing process.

Operating expenses on a GAAP basis were \$24.9m for the first quarter of fiscal 2004. This compares to \$23.1m for the fourth quarter of 2003, and \$21.5m for the same quarter one year ago. Q1 operating expense includes approximately \$1.8m of stock-based compensation. Excluding the \$1.8m of stock-based comp, we arrive at non-GAAP operating expenses of \$23.1m. Operating expense in the first quarter included a \$400,000 one-time charge for termination of a regional distribution agreement in Europe.

GAAP net profit for the first quarter was \$557,000, or \$0.01 per basic and diluted share, compared to a net profit of \$452,000, or \$0.01 per basic and diluted share of last quarter, and a loss of \$10.7m, or \$0.19 per basic and diluted share in the same period one year ago.

Total stock-based compensation for the first quarter was \$2.2m. Excluding this, we arrive at first quarter non-GAAP net profit of \$2.8m, or \$0.05 per basic, and \$0.04 per diluted share. This compares to non-GAAP net profit of \$3.5m or \$0.06 per basic, and \$0.05 per diluted share for Q4 2003, and a loss of \$5.9m or \$0.10 per basic and diluted share in Q1 of 2003.

A quick note on the top and bottom line performances related to the case refinement restatement we announced in July of 2003. Restatement contributed \$1.9m of revenue and associated income in the first quarter of 2004. Again, a full non-GAAP income statement and a reconciliation of GAAP to non-GAAP financials is available on our press release.

Now, on to the balance sheet. Cash, cash equivalents, and marketable securities at the end of Q1 of 2004 was \$48.2m, compared to \$47.7m at the end of 2003 yielding a positive cash contribution of approximately \$0.5m. Typically, the first quarter of our fiscal year includes a number of annual cash expenditures. Despite the seasonal pressure on first quarter cash flow, we are pleased with our cash position and asset management, including DSOs or day sales outstanding and receivables of approximately 57 days.

Now, let's spend just a few minutes on the second quarter and review our guidance for full year 2004 and 2005. Again, I'll first provide GAAP guidance and a reconciliation to non-GAAP guidance for your comparison purposes. Q2 revenues are projected to be in the range of \$41.5m to \$43.5m. Ortho channel, GP channel, and international are expected to comprise approximately 51%, 34%, and 10% of Q2 revenues respectively. The remaining 5% approximates training and ancillary product revenues. Case shipment volumes are projected to be in the range of 23,700 to 24,900 cases. Our Q2 revenue projection includes approximately \$1.2m of impact from the case refinement restatement we announced last July, and also reflects ASPs of just over \$1600. Q2 gross margins on a GAAP basis are projected to be in the 66% to 67% range. We project that gross margins will include approximately \$400,000 of stock based compensation charged to cost of revenues. Taking this into consideration, non-GAAP gross margins are projected to be in the range of 67% to 68%.

Operating expenses on a GAAP basis are projected to be in the \$25.5m to \$26.5m range for Q2. Operating expense will include approximately \$1.6m in stock based comp. Excluding this we would arrive at non-GAAP operating expenses of \$23.9m to \$24.9m.

GAAP net profit is projected to be in the range of \$1.5m to \$3.5m. Taking into account the stock based compensation amounts I just discussed, non-GAAP bottom line performance is expected to be a profit in the range of \$3.5m to 5.5m.

Let me turn to guidance for full year 2004 for a couple of minutes. We expect revenues in the range of \$165m to \$175m. This is an increase of \$5m from the guidance we provided on our January call. The orthodontist channel, GP channel, and international channel are expected to comprise 49%, 36%, and 10% of 2004 revenues respectively with the remaining 5% approximating training and ancillary revenues. Case volume for the year is projected to be in the range of 96,000 to 102,000 cases. Full year

revenue projection also includes approximately a \$5m impact for the case refinement restatement we announced last July.

Full year GAAP gross margin is projected to be between 66% and 68%, again an increase from previous guidance. Cost of revenues will include approximately \$1m in stock based compensation; adding this back we arrive at non-GAAP gross margin guidance of 66.6% to 68.6%. Again that's 66.6% to 68.6%.

Full-year operating expense guidance on a GAAP basis remains constant at a range of \$104.1m to \$107.6m. Though revenues are increasing, operating expense guidance remains constant due to the decrease in stock-based compensation projections. Stock-based compensation included in operating expenses for 2004 is projected to be approximately \$4.9m. Again, excluding stock-based compensation, we arrive at non-GAAP full-year operating expense guidance of \$99.2m to \$102.7m.

We project full-year GAAP net profit in the range of \$4m to \$10m. Full-year non-GAAP net profit is projected to be in the range of \$10m to \$16m. Additionally, GAAP EPS for 2004 is expected to be in the range of \$0.06 to \$0.15, while non-GAAP earnings per share is expected to be in the range of \$0.15 to \$0.24.

Let me move on to the balance sheet projections for 2004. As we said last quarter we believe there may be quarter-to-quarter cash utilization fluctuations. At the end of the year however, we expect that our total cash contribution to the business will be neutral, but slightly positive. With that said, cash balances at year-end 2004 are estimated to be in the range in \$47m to \$50m. Day sales outstanding are expected to average in the range of 56 days to 58 days. We project capital expenditures in the range of \$10m to \$12m for the year. Depreciation and amortization is expected to be in the \$10m to \$11m range for full-year 2004.

For 2005, revenues are estimated to be in the range of \$220m to \$240m. GAAP gross margin are estimated to be up to 70%. GAAP net income for 2005 is estimated to be up to 16% of sales. GAAP net income includes approximately \$1m non-cash stock-based compensation, basically that charge will be complete in the first quarter of 2005. Now, we'll take some questions. Operator.

QUESTION AND ANSWER

Operator

Thank you. Ladies and gentlemen, if you would like to register a question please press the one followed by the four on your telephone. You'll hear a three-tone prompt to acknowledge your request. If your question has been answered, and you like to withdraw your registration, please press the one followed by the three. If you're using a speakerphone, please lift your handset before entering your request. One moment please for the first question. Ladies and gentlemen, as a reminder if you wish to register a question please press the one followed by the four on your telephone. Our first question comes from the line of Ed Shenkan, Wells Fargo Securities.

Ed Shenkan - Wells Fargo Securities-Analyst

Hi, good morning gentlemen. I want to ask a question broadly about the industry and what you're seeing. Would you see any either braces manufactures or new competitors that you expect to introduce similar products to Invisalign in the upcoming years or three years? And similarly could it make strategic sense for Invisalign to merge with any braces manufacturers and increase distribution?

Eldon M. Bullington - Align Technology-Vice President, Finance and CFO

Thanks for the softball question Ed. I guess the first statement I will make is to your second question. This wouldn't be the time or place for us talk about broader strategic initiatives, anything on the M&A side. But let me say in general we believe we got competition all over the place. We try to act it like everyday, and we've got a large fire under us in terms of creating a sense of urgency. There are a range of choices for clinicians today to straighten teeth, and there are very good products out there in the marketplace for them to use and, so we have to work very hard to make sure that our value proposition for the doc and the patient are superior to what everyone else can bring to the market. Beyond competing for those case starts, we are competing for the attention of non-consumers in the marketplace for whom conventional braces and brackets don't meet their needs or potential may not meet their needs, and so we are trying to get to — we're trying to get to the point where we can attract people that wouldn't even think about getting braces to get their teeth straightening the Invisalign way. All that said, we've got — we believe are very strong fresh intellectual property, as well as tremendous manufacturing and technology competencies that would make it difficult to follow us in the courts, or in the real world. And, anybody who should say what we are doing today is, going to probably be late by the time they get there anyway. Yeah we worry

a lot about competition Ed. Yes, it's the nature of the competitive marketplace, but we believe we are prepared for. And again, I'm not going to comment the second issue at this point.

Ed Shenkan - Wells Fargo Securities—Analyst

Thank you. As a follow-up. Physicians more eager to try Invisalign than doctors who haven't tried it previously, now in a year ago. Is the introduction from the second or third patient to the 50th patient, is it accelerating, can you talk a little about that? Thank you.

Thomas M. Prescott - Align Technology—President, CEO

Maybe there is two dimension to that, I think as Eldon talked about a little bit, we are not going to provide any granularity here. But we did see utilization same practice case starts go up in the ortho channel at a significant level. And that's actually a good sign to say that the people are starting to accelerate their practice there. Anecdotally or quantitatively, and we actually provide detail there, but anecdotally, we do feel that there are some clinicians who perhaps didn't have the best experience with the products early on, that have come back, and have had some good results and have been able to create some very good clinical results for patients. So, I think it's a hard one to answer. We are going to get lots of feedback in the next week or so. We are about to go up to the American Association of Orthodontics, AAO, the annual meeting. And its always an intense week, and we get lots of feedback, and lots of good ideas about from our doc. So, I'll be ready to answer this more concretely maybe on the next call.

Ed Shenkan - Wells Fargo Securities—Analyst

Thank you.

Thomas M. Prescott - Align Technology—President, CEO

Sure, thanks Ed.

Operator

Our next question comes from the line of Tao Levy. Please proceed with your question.

Tao Levy - Deutsche Bank - Analyst

Hi guys, this is Tao.

Thomas M. Prescott - Align Technology—President, CEO

Ні Тао.

Tao Levy - Deutsche Bank - Analyst

Just can you speak of a quick numbers for me which I missed — orders received in the quarter?

Thomas M. Prescott - Align Technology—President, CEO

New cases received were — we had 23,700 net new cases received in Q1.

Tao Levy - Deutsche Bank - Analyst

And the average cases per business?

Thomas M. Prescott - Align Technology—President, CEO

376.

Tao Levy - Deutsche Bank - Analyst

Great, thanks. In terms of the '04 guidance, you bumped that up by \$5m?

Thomas M. Prescott - Align Technology-President, CEO

Yes.

Tao Levy - Deutsche Bank - Analyst

Yet your shipment volume didn't change, are you looking for higher ASPs, or is there anything going on there?

Thomas M. Prescott - Align Technology—President, CEO

I'll let Eldon comment there.

Eldon M. Bullington - Align Technology—Vice President, Finance and CFO

Tao its probably a couple of things. One, I think is doing some true ups in our guidance, for one thing. And two is — as I mentioned, we are seeing a little bit higher ASPs, and part of that is driven by — we are seeing a little bit of an evolution of our mix relative to full large treatments than what we expected. And also,

kind of the evolution of our case refinement revenue flow through the business is picking up a little bit quicker than what we had anticipated. So, that is having some uptick on our overall average ASP.

Tao Levy - Deutsche Bank - Analyst

Okay. And if I look at where you guys came out on a channel basis, you are little lower than you are looking for on the orthodontics side, and a little higher on your GP side. Do you think there is any cannibalization possibly going on from the GPs at this point?

Thomas M. Prescott - Align Technology—President, CEO

Again, maybe we were off in what model you had Dale, but from our perspective, we were right about where we are expected to be from a channel perspective which actually is really good news for us. We think we have pretty good handle on where the levers are in the business. The other question around that whole issue is the cannibalization, not only is there not cannibalization, we think the acceleration in ortho practices is because of working to build this cooperative market model where Ortho's work with GPs in areas that are already referral partners. And as they help them be comfortable doing straightforward simple cases, many people who had not even sought orthodontic treatment, they might be in a dentist office to get your teeth whitened to do some basic restorative. And if the ortho works with GP in a cooperative way, the GPs offices increasing their awareness and knowledge understanding of malocclusion, the chairside support, the hygienist, they are all better able to spot malocclusion and talk to patients and educate them about it. Increasingly, those people are wearing aligners as part of our professional discount program as a front line of education, and those with anything not straightforward and simple are not going to the dentists anyways and we are seeing that happen. So, I think it is just the opposite, many other people, the GPs are doing, we are not seeking orthodontic treatment to begin with.

Tao Levy - Deutsche Bank - Analyst

Okay and then if I could add a couple more and I'll get back in the queue. Your sales and marketing expense went up significantly as you guys had mentioned in prior conference calls. What type of payback, when do we see the payback on the significant investment that you are currently making?

Thomas M. Prescott - Align Technology—President, CEO

So really sales and marketing is really two fold. One component is a slight uptick in advertising, and we are — and so when we increase consumer marketing, several things come along with that. One, we increase direct-to-consumer program both direct mail and TV spots and fulfillment and along with that comes kind of a kind of linear increase in call center costs. So, as we step up or increment up direct-to-consumer promotion, there is a couple of piece that come along with it. The second part of that is program spending, we have substantially stepped up our clinical education efforts. We are expanding the number, the types and we believe substantially the quality of the workshops, study clubs, professional training environments the clear feedback from all our clinicians is this brings tremendous value to them. So, we see pay back from direct-to-consumer programs within a quarter or two as leads turn into cases. We generally see a pay back range from a quarter to three quarters in education initiatives, and we track and measure those very carefully at a single practice level for the people who have participated. The third piece of this is some expansion of sales force which we forecasted and talked about, and the money we are spending on the increases in marketing and sales in Q1, and the direction we given for OPEX in general for the year are very much consistent with what we talked about in Q4 when we did the year-end release. So, we are right on where we said we are going to be in terms of incrementing up spending in two key areas. One, sales and marketing to build the business, grow the topline, get better results, and two, on the R&D and technology development side where we are substantially increasing the leverage on automation systems, all those other sort of things. So, we are actually right about where — Eldon talked about a one-time cost we had, but we are right about where we expected to be in terms of controllable OPEX or operating expense.

Tao Levy - Deutsche Bank - Analyst

Okay great. Thanks a lot, and just one final one. In terms of your guidance for '04 on EPS front Eldon, what is the tax rate that you are using if any in the \$0.15 to \$0.24?

Eldon M. Bullington - Align Technology—Vice President, Finance and CFO

Tao, consistent with what we talked about in the past, the taxes that are flowing through our income statements this year are pretty much just residuals for some foreign tax and some local tax. We have not recorded the roll over to a reserve on the books type of accounting model. So, it was \$133,000 of tax charged to the P&L for Q1, and that's not going to be dramatically out of line with the relative dollars charge through time. It is not as much as a percent of operating income, it is just where we have to pay residual foreign taxes this year. We are not providing at this point in time for state or federal against our NOLs.

Tao Levy - Deutsche Bank - Analyst

Okay.

Eldon M. Bullington - Align Technology—Vice President, Finance and CFO

That is an event we will address in the future, but is not coming near term.

Tao Levy - Deutsche Bank - Analyst

Thanks a lot.

Operator

Ladies and gentlemen, as a reminder if you wish to register a question please press the one followed by the four on your telephone. Our next question comes from the line of Brian Delaney of Entrust.

Brian Delaney - Entrust

Good gentlemen and congratulations on the quarter.

Thomas M. Prescott - Align Technology—President, CEO

Thank you.

Operator

I am sorry.

Thomas M. Prescott - Align Technology-President, CEO

Hello. Operator. Do have one or two question in, please?

Operator

I am very sorry. My microphone was still open, terribly sorry.

Thomas M. Prescott - Align Technology—President, CEO

Thank you. Please continue Brian.

Brian Delaney - Entrust

I am sorry. In terms of the training of the GP the 700 GP that you trained in the quarter, how does that compare to kind of what your internal forecasts were, and is that still then on track for the 5000 plus for this year?

Thomas M. Prescott - Align Technology—President, CEO

We have typically — well let me answer the broader question first Brian. We have typically have said we will do 4000 to 5000 and the thing is a little closer to four just in doability. We traditionally have a slower start in certifications in Q1 just because you enroll them typically the quarter before and that's the holidays and we really didn't do our first certification of the year until very late January, early February. The rate of certifications is right where we ought to be, and we are forecasting a little about 700, but not by a lot. We didn't expect a huge number in Q1. We were very comfortable that we will do 4000 or thereabouts for the year and that is kind of our game plan.

Brian Delaney - Entrust

So forth to — okay. So, if I look at kind of last couple of years it was running 5000, how should I think about why — it is just a capacity issue in terms of not being able to do more than 4000 and going back to the kind of historical levels of GPs trained?

Thomas M. Prescott - Align Technology—President, CEO

So, we've always talked about kind of up to 5000 as an upper bound and there is a reason it's an upper bound — I mean we could put an awful lot more bodies in hotel rooms on Friday and Saturdays all over the country, but there is a practical learning here that has occurred that says there is a whole system approach. It starts with pre-work before the certification where the field team actually contacts and sets the right expectations, does some front-end learning. They bring their pre-work to the certifications; there is an intensive session at certification. There is a fast start program that occurs after the certification and so capacity kind of writ large is company capability to properly train them, support them, get them started, make sure they get great results. At some level if we had, you know, two times the number of people in the field, if we had more clinical support resources, broader on line — I mean if the whole thing was scaled up, we might dial that up more. But we're very comfortable where we are. Our principal goal is to get the right docs into chairs, have them trained in a professional manner, so that they're very pumped up when they go back and then have them most importantly getting great results for patients. And I think, the numbers 4000 and above, we've have been around that number and in the last couple of years, I think the number approximately was around 4100 for all of '03. So, again, we've said around 5000 or up to about 5000, but that depends what you said about four.

Brian Delaney - Entrust

Okay. I mean my concern was that it's not just a lack of demand, as you know, the demand still out there for the number of GP that you haven't trained. So, the trend I'm seeing is a function of what you're talking about? I mean that's what I was trying to focus on?

Thomas M. Prescott - Align Technology—President, CEO

Yes. We've got about 7% of the GP population out there, that do the business certification.

Brian Delaney - Entrust

Thanks and then just a clarification on the case refinement. You said that the contribution was \$5m and associated income, so in your EPS guidance, is there \$5m — I should assume it's a 100% margin this restatement that all drops to the bottom line?

Eldon M. Bullington - Align Technology-Vice President, Finance and CFO

For the most part.

Brian Delaney - Entrust

Okay, So, can you help me then, if I were to move the benefit you have in your guidance this year for EPS and then bridge me to kind of what the EPS guidance is for '05? Except it's a huge ramp after I take out what was case refinement benefit?

Eldon M. Bullington - Align Technology-Vice President, Finance and CFO

Brian, we view case refinement as an ongoing part of our revenue and basically the way that process works, case refinement for one case has included in our pricing and we defer that and recognize it in one or two points either when the refinement is actually shipped or if the case concludes and the refinement is never requested by the clinician, or if beyond the first refinement is included, clinicians can buy additional cases that we don't view that as an adjunct to our business is part of our business and part of our normal revenue flow. So, we don't include it or exclude it or view it as an extraordinary item, so I don't view the business that way and I don't see the value in analyzing it that way.

Brian Delaney - Entrust

Okay and I was just trying to say my impression was that this was a restatement that will impact '05 but then going forward it will no longer be a contributor. So, I was just trying to bridge from where you are in terms of bound line guidance this year to next year, and I guess my assumption was that it was like a case refinement benefit we had this year wasn't going to repeat itself in '05? And maybe that was wrong on my part.

Eldon M. Bullington - Align Technology-Vice President, Finance and CFO

Okay or maybe I didn't completely understand your question, if you're relating to the revenue restatement numbers that we talked about then that's an issue that is pretty much done in 2004 and you would not carry forward other than just a very small residual amount in 2005. So, if I misunderstood your question, I apologize. Case refinement and the restatement are two completely different things.

Brian Delaney - Entrust

Okay and then I guess — maybe I missed on something on the restatement portion — how much was the contribution for the restatement in '04?

Eldon M. Bullington - Align Technology-Vice President, Finance and CFO

It's \$5m.

Brian Delaney - Entrust

Okay. So we're talking about the same thing. Okay, thank you very much.

Eldon M. Bullington - Align Technology—Vice President, Finance and CFO

And to your point, that basically falls straight through.

Brian Delaney - Entrust

Okay and it will not recur in '05?

Eldon M. Bullington - Align Technology—Vice President, Finance and CFO

That's correct.

Brian Delaney - Entrust

Okay. Alright. Thank you very much and keep up the good work.

Eldon M. Bullington - Align Technology-Vice President, Finance and CFO

Brian, thank you.

Operator

Our next question comes from the line of Mary Ishanti of A.H. Ishanti Capital Growth.

Mary Ishanti - A. H. Ishanti Capital Growth-Analyst

Thank you. Good morning, I am wondering if you could talk a little bit about the marketing partnerships you negotiated with Care Credit and sort of, you know, how long you have had it, and what your doctors might be seeing in terms of is there increased interest or are they being more aggressive with the product now that they have the opportunity to get paid upfront on the product.

Thomas M. Prescott - Align Technology—President, CEO

Well, you know, I guess, never want it. It's very new. We have been working for the last year to year and a half on a whole range of alternatives that, you know, we don't want to be the Bank and traditionally orthodontists were the Banks. They basically set for a flat price, I will charge you X and I won't pay your interest — I won't charge you interest and what they were basically doing was leveraging their, in a sense, financing their time because their running costs were not as high as they are under this line. In this line it's little bit of reverse troop. The doc has more costs upfront as they pay our fee roughly six months into the process, and so they have been more driven on a cash basis to [Inaudible] collect a little more upfront of \$1000, \$1500, or \$2000. For some patients, that's just too much money to put upfront and — versus pay \$250 to \$500. What this allows them to do and this is a change for orthodontists, not all orthodontists want to do this, some that have significant expansion going on in their practices, in effect it takes the pressure of working capital for them, and they are really jumping on this, because they find if they have gone from say 10 cases a year to 50 or 75 cases a year, they can easily get out of this step with the cash flow that are actually coming in from the patient over time. So, this allows them especially during those periods of expansion, at a very low rate, where we effectively brokered interest rate, in effect helped the financing companies see the size and desirability opportunity and a very good credit list in all of these, you know, wealthy practitioners represented and we can't put buyer and seller together and help create a program. And so, what I would say is it is very early for me talk about broad trends, but we think this can both be important at dentist's office, the GP as well as the orthodontist, and again it allows them to overcome one of the key questions setting at cheer side for the patient where, boy! that's a lot of money — I don't know if I dropped with \$1000 to start or \$1500, they can basically say you can get \$30 today with almost no down payment, you can basically pay in a year, and then take a year after that to pay over, you know, 12 payments. As there are no financial implications for our line we are not guaranteeing anything, we have no reserves, there is no — we are not backing it by the appearance, so you know, it's just us helping our docs broaden their practice, have better offerings, and hit a part of the market that they may have been missing.

Mary Ishanti - A. H. Ishanti Capital Growth-Analyst

How long is the agreement? Is there an initial term for the agreement or is it just sort of indefinitely or does the financing company have the ability to re-examine it at some point?

Thomas M. Prescott - Align Technology—President, CEO

Yes, there is no actually no agreement between Care Credit and Align, there is no financial relationship, there is no contract with us. What we did, we did program development, we haven't found best in class companies that could do — there is — we've been working like this for about a year, a year and a half. And what we really thought was we considered should Align do this, should Align create an offering here? And we get back and say, we are not a financing company, we don't have a cost of capital and our balance sheet structure and everything else that would make sense for that. So — but we are now looking for people that understood Healthcare and loaning — working with doctors for patient based financing, that will use their professional practice environment, single office environment. So, we act as a facilitator, developed a program of care credits, tuned it up for orthodontists and GPs and roll it out to our customers and it's doing pretty well for just being a starter, so maybe I wasn't very clear, there is no agreement to stay with us and it's a business development for them and facilitation for us.

Mary Ishanti - A. H. Ishanti Capital Growth-Analyst

Okay, and you started this during this quarter?

Thomas M. Prescott - Align Technology—President, CEO

Yes, we launched it this quarter and there will be more discussion about it at AIO (ph) next week.

Mary Ishanti - A. H. Ishanti Capital Growth-Analyst

Okay, thank you.

Operator

Ladies and gentlemen, as a reminder to queue operate question, please press the one followed by the four on your telephone. Our next question comes from the line of Tao Levy with Deutsche Bank. Please proceed with your question.

Tao Levy - Deutsche Bank-Analyst

Hi guys. Just a couple of clarifications. Eldon, what was the net profit non-GAAP that you are guiding for the full year '04?

Eldon M. Bullington - Align Technology—Vice President, Finance and CFO

Okay Tao, for the full year GAAP — for full year 2004, our GAAP net profit was about \$10m and our full year non-GAAP net profit for 2004 projected in the range of \$10m to \$16m.

Tao Levy - Deutsche Bank—Analyst

Okay and that compares to the last quarter, do you remember what your guidance was last quarter, just five and a half to 12.

Eldon M. Bullington - Align Technology-Vice President, Finance and CFO

Correct?

Eldon M. Bullington - Align Technology—Vice President, Finance and CFO

That's correct. So yes, that's correct I guess. So you see there is a \$4m to \$5m uptick there from our — our guidance last quarter.

Tao Levy - Deutsche Bank-Analyst

Okay and what is it for — for '05, the net profit non-GAAP? And I apologize I can't write as quick as I probably should.

Eldon M. Bullington - Align Technology—Vice President, Finance and CFO

Not a problem. Glad to help. For 2005, basically what we talked about and what I said and I gave it in percentages. So, I will give you the pieces again. For 2005, what I quoted a few moments ago was a revenue range of \$220m to \$240m and a GAAP gross margin of up to 70% and a GAAP net income of up to 16%, and included in that the stock drops to a small number of \$1m. So in terms of converting that to a non-GAAP bottom line, now let's do the math.

Tao Levy - Deutsche Bank-Analyst

Perfect and I guess as was the thing with last quarter, you didn't change your '05 revenue guidance, and I assume that you are just waiting for some more visibility. I don't know how this year goes.

Eldon M. Bullington - Align Technology-Vice President, Finance and CFO

On our call last quarter, the revenue guidance is the same. What our bottom line guidance was, we gave a range of 10% to 16%.

Thomas M. Prescott - Align Technology—President, CEO

Right you tightened that up to 16.

Thomas M. Prescott - Align Technology—President, CEO

Right I am saying up to 16.

Tao Levy - Deutsche Bank-Analyst

Great. On the revenue line, when do you feel comfortable in '04 to possibly start adjust or maybe — maybe move up the '05 revenue guidance.

Thomas M. Prescott - Align Technology—President, CEO

It is still early in the year. As we said a year ago on the — I can't answer that question absolutely. But as we see the year go on and we understand the run rate and the dynamics of the business will — you know we will — if there is any difference in the view we have got out there, we are obligated to talk about it. It is early for me to say when and I don't know if it will be this time next quarter, perhaps third quarter. Certainly by the fourth quarter we will be able to — you know if there is a change. But you know we are — we are going to talk about it as soon as we can.

Tao Levy - Deutsche Bank-Analyst

Great. Thank you very much.

Operator

Ladies and gentlemen. As a reminder if you wish to register a question please press the one followed by the four on your telephone.

Thomas M. Prescott - Align Technology-President, CEO

Operator, maybe we will take one more question if there is one out there. Otherwise we can bring this to a close.

Operator

At this time there are actually no questions. I will turn the call back to you.

Thomas M. Prescott - Align Technology—President, CEO

Thanks. Thanks very much. Well — let me just say that the entire Align team is energized by the opportunity of taking this great new product in Align and building a great company. The field is set up for us here. We look forward to sharing our progress with you in upcoming calls and so thanks for being on the call today. If you have any questions we can be reached at 408-470-1000. Thank very much, operator.

Operator

Ladies and gentlemen. That thus conclude the conference the call for today. We thank you very much for joining and ask that you please disconnect your line.