FINAL TRANSCRIPT

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Event Transcript

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CORPORATE PARTICIPANTS

Jay Wadekar
Able Laboratories - President and CEO

Bob Weinstein
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CONFERENCE CALL PARTICIPANTS

Jim Flanagan
IR Strategic Advisors - President

Jay Jay Wadekar

Our first question

PRESENTATION

Jim Flanagan - *IR Strategic Advisors - President*

Welcome to the CCBN Virtual Healthcare conference, cosponsored by Lippert/Heilshorn & Associates and RedChip partners.

My name is Jim Flanagan. And I'm President of IR Strategic Advisors, a Boston area investor relations and public relations communications firm. I'm also a member of CCBN's advisory board. And I'll be serving as your moderator today for this Virtual Healthcare conference.

For our audience who will be participating live today, I want to remind you and introduce that you can submit a question at any time by simply typing your query into the question field in the lower left-hand side of the Webcast player. I will present these questions during the question-and-answer session at the end of the company's prepared remarks.

Should we have more questions than time allows for, please be sure (ph) that we will forward all questions to company management for them to respond directly.

Our next presenting company is Able Laboratories, stock symbol ABRX. Able Laboratories develops and manufactures generic pharmaceuticals.

Since March 2001, the company has received 21 abbreviated new drug application approvals and several pending ANDAs, under review by the FDA. The company manufactures tablets, capsules; and is one of five suppository manufacturing facilities in the United States, and has recently expanded its manufacturing capacity.

Representing Able Laboratories today is Jay Wadekar, President and CEO. Jay has over 20 years of experience in healthcare, biotech (ph) in technology growth companies. Mr. Wadekar has been instrumental in the successful turnaround of the company.

Mr. Wadekar, please feel free to begin your presentation.

Jay Jay Wadekar

Well, thank you very much. And good to be here on CCBN. Thank you for the opportunity. I want to welcome everybody.

But before we begin, with me is Bob Weinstein, who has recently joined us, as you know, as our Vice President and Chief Financial Officer.

And prior to beginning the presentation, we'll do the Safe Harbor statement, which Bob is going to do. We'll do the presentation, and we'll follow the format of taking some questions.

Bob Weinstein - *Able Laboratories - Vice President and CFO*

Under the Safe Harbor provisions, except for historical facts, the statements in this presentation, as well as oral statements or other written statements made, or to be made, by Able Laboratories, Inc., are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, and involve risks and uncertainties.

For example, statements about the company's anticipated growth and future operations, the current or expected market size for its products, the success of current or future product offerings, the research and development efforts and the company's ability to file for and obtain U.S. Food & Drug Administration approvals for future products are forward-looking statements.

Forward-looking statements are merely the company's current predictions of future events. The statements are inherently uncertain, and actual results could differ materially from the statements made herein. There is no assurance that the company will achieve the sales levels that will make its operations profitable, or that FDA filings and approvals will be completed and obtained as anticipated.

For a description of additional risks and uncertainties, please refer to the company's filings with the Securities and Exchange Commission, including its annual report on Form 10-K, for the

year ended December 31st, 2001; and its Form 10-Q for the quarter ended September 30th, 2002.

The company assumes no obligation to update its forward-looking statements to reflect new information and developments.

Mr. Wadekar will begin his presentation on your presentation slide number three.

Jay Wadekar - *Able Laboratories - President and CEO*

Well, thank you very much, Bob.

We - as you're looking at the slide and the company overview, we're a generic drug manufacturing company. Our capabilities include manufacturing tablets, capsules, suppositories and sustained-release formulations.

In the third quarter 2002, we reported net sales of $15 million and net income of $3 million. This translates into an earnings per share of 25 cents on a basic (ph) and 19 cents fully diluted.

We currently have 275 employees. And our growth has been driven by approximately 22 FDA approvals we received since the year 2001. Almost 18 of these approvals have been received in the last 15 (ph) months, which has really fueled the growth that you see.

We have a robust pipeline, with approximately 12 (ph) ANDAs under review by the FDA currently. They're pending approval. And our objective is to continue to be aggressive in R&D.

On the next slide, which is the investment highlights slide, we want to point out that Able has expanded very rapidly. We have rapidly expanding customer base. We have been able to enter and take (ph) customers in all trade classes, such as wholesalers, like McKerson (ph) and Cardinal (ph), and AmeriSource (ph) and Bergan (ph), as well as the chains - CVS (ph) and Walgreen's being some of the top names - as well as some of the smaller chains, regional chains and wholesalers.

Over the past six quarters, we (ph) had increasing net income, increasing gross margins. And some of these increasing margins have been generated by niche products that, we experience, give us above-average margins.

As discussed earlier, we have a very aggressive R&D program. We continue to invest heavily in R&D and will continue to do so in the year 2003 as well. Our objective is to target over 15 to 20 different products for development in the year 2003.

We have had an excellent track record with the FDA. Our facility is fully compliant with the current good manufacturing practices. And we have been receiving approvals in an average of about nine to 10 months.

We also have over $50 million of net operating loss available to us. And that translates essentially into not having to pay federal taxes until that $50 million of net income is used up. We will, however, start paying state taxes in the next quarter.

And lastly, we have a highly talented and (ph) experienced management team. Most of the senior managers come from the industry. They have been with generic drug manufacturing companies that have been very successful, that have grown. And this management team has contributed tremendously in the growth of several big names in the - in the generic sector right now. We're very fortunate to have them with us in Able.

Let's first look at what our initial strategy was. And then we'll come back and talk about what the current strategy is.

When we started this program of turning around Able, which was a troubled discuz (ph) company, our initial focus was entirely on developing those products that we can immediately bring to the market. In other words, we did not want to wait for the patents to expire and wait for the sales to start happening.

So the initial product line that you see - with the exception of one, Tremedol (ph), where we waited for the patent expiration (ph) - almost everything else - as soon as we got the approval, we were able to start selling.

We also focused on those items that were between $25 million and $100 million total sales. Since most of - since almost all the products that we develop were off-patent (ph) mature (ph) products - there were other competitors as well - they were generic for quite some time. And the total brand and generic sales for these items were between $25 million to $100 million.

We believe that that's the range where you get less (ph) competition. There are less suppliers. And therefore, there is better opportunity for pricing and margins. We also looked at those drugs where we felt there was a positive trend, or an upward trend, in mainly price, and sometimes in volume.

There is a belief out there that generic drug prices always decline, which is true as the - as the drugs come off patent. But then

over a period of time, the prices (ph) not only stabilized, but they sometimes start to go back up again. And we were able to spot a few items that were showing us (ph) increase in pricing. And we were able to pick them for development.

And lastly, we have also targeted those items where we believe there's a limited complication, such as a suppository formulation. These are - these are not very big items, very big products. However, there's (ph) good opportunity, both in terms of being the - one of the two or three suppliers and getting better margins.

On the next slide, where we talk about the product portfolio - what would be currently selling - if (ph) - I'll go by the brand name, so that it makes it easier, which is in the second column.

The recent approvals we got - Tylenol III with codeine, or Tylenol number three that has Tylenol and codeine, and (ph) as well as number four - we have seen some price increase in there. These are controlled substances as defined by the DEA. They require special handling, because there's codeine in it. The company is very well established to handle controlled drugs. We are qualified to deal with class two through class five; depending on the addiction potential, you get the classification.

We've been handling class two through class five, and staying in that - in that - in that arena also differentiates us a little bit from some of our competitors, who don't handle as much controlled product as we do.

The next brand items, which is Feroset (ph) and Asjek Plus (ph) - these are migraine headache formulation. There was a price increase in these drugs as well. And we were able to time it right.

If you continue down on that page, the (ph) next one I want to point out is the last item on the - on the page, Endocin (ph) sustained release (ph). There's only one competitor on that product. But they're (ph) better than average margins that (ph) we make.

If you go to the next slide, the brand name Ritalin - we have (ph) the entire Ritalin family; the measured-release as well as the sustained-release formulation. This is the attention disorder drug - controlled substance as well. And because of that, we see fewer competitors than otherwise.

Down the page, you can see the names Adipex C (ph), as well as Fastin. These are obesity drugs; they're for weight loss. Again, there's been a significant price increase here as well. And we were able to time it right.

The next one that I want to point out is Darvocet. This is one of the larger generic drug (ph) in the U.S. - in the U.S. It probably ranks number three in terms of number of units dispensed, as well as the dollar volume as well.

We identified this product because it's very high in demand. And we're able to get a good market penetration with this as well.

And lastly, the brand names which we left (ph) blank - Vicodin, or the hydrocodone, with Tylenol - you must have seen the recent approval company got on the entire hydrocodone line. There are about nine different formulations. We have seven approvals that (ph) we received to date. We have not launched the product. We will be launching it sometime in the middle of first quarter, when we complete the validation.

Again, Vicodin, Locet (ph), Lortab, et cetera - these are highly dispensed. They probably are - as a family, this is probably the number-one dispensed drug in the United States. IMS (ph) sales data, where we show the total brand and generic sales, show this product to be over $1 billion in sales.

So this is the current portfolio that we're marketing.

On the next slide, we talk a little bit about (ph) our new initiatives. And the new initiatives - the basis of the new initiative is to continue doing what we have done in the past, which is taking these mature generic drugs, which are off-patent (ph), or where there's no patent problem (ph), and identified (ph) those where we see both the price increase and all the (ph) usage increase - and develop those.

The first to market - the traditional definition of this is a patent challenge, patent litigation, whereby if you're the first one to file, certify that you're not infringing the patent or the patents are invalid, and you are able to win this in the - in the court, you'll get six-month (ph) exclusive. This is a very lucrative strategy, obviously. But it does require a significant amount of investment.

This is not what we consider first to market. We're looking at first to market as those items where we believe, for some reason or the other, there is no generic competitor. And probably one of the reason is that brand is a small-brand (ph) drug. Sales could be between $20 million, $25 million or $30 million at the most, and no more than $50 million of brand sales. Brand (ph) is the

only one that is making it the active drug of the ABI (ph). And there are - there is no ABI (ph) sourcing. There's no agerment (ph) manufacturer for the active drug.

We have been able to successfully identify very high-quality manufacturers of active drugs, or bald (ph) drugs; pay them the fees for exclusively developing the product for us, and signing the agreements with them - exclusive agreements with them. This forms the basis for our going forward.

First to market with smaller (ph) products, we believe, is going to give us an opportunity to have less competition and better-than-average margins.

Now, within that also, we look for items that are technically difficult to make. The (ph) small drugs, but nobody has made a generic yet, because maybe it's too small for people in major companies to focus on. And we will also look at those where we believe there's technical barrier to entry.

With that strategy, we are targeting a portfolio of approximately $250 million to $300 million in brand sales, where we believe - that consist of approximately 10 different drugs - where we believe we could be first to market, made amends (ph) the only generic for quite some time, or face, at the most (ph), one of the competitors. We think that this is a niche area that Able can really capitalize on.

If you look at the next slide, R&D expenditures - research and development is the cornerstone of the company. We have been very aggressive with the program. Our R&D expenses have grown very steadily. And third quarter was approximately $2.2 million spend on R&D.

We have said, in the conference call for the third quarter, that we'll continue to see (ph) R&D expenditure increase in the future. We expect that 2003 will be - will be considerably higher than 2002 in R&D expenditures.

On the next slide, we talk about our pipeline. As we said, we currently have about 12 potential products first to market. Fourteen percent of the workforce, or approximately 45 to 50 scientists (ph), formulators, chemists and the support staff are working in the research and development area. This is out of a total strength (ph) of about 275, 280 people that we currently employ.

Our fiscal 2002 budget was $6 million. I believe we are a little bit over that already. And 2003 will be - will be higher as well.

The next slide talks about the market potential. The source of this data is IMS, an industry publication that tracks sales of prescription products at the pharmacy level. Obviously, what the pharmacist sells it for is not the price we get, since there are multiple people within the chain till the product gets to the - to the pharmacy.

Therefore (ph), the sales that we recognize as an industry can be significantly less than what these numbers are. However, these numbers give an approximate idea of the type of markets we are - we are operating in.

The markets that we currently address are over $2 billion in IMS sales numbers. We have product (ph) spending over $1 billion. And what we have under development is approximately $2 billion in retail sales.

Out of this two billion, we believe 270 million could form the basis of first-to-market opportunities for Able. Out of these, we have four applications pending that give - we have the (ph) sales of about $70 million, where we believe we could be first. And there are eight in R&D. And we expect to file most of them the next eight to 10 months.

The next slide is about our net sales growth. This is the graphics (ph) to give you an idea about the rapid growth Able has experienced in the - in the past five, six quarters. We started the second quarter with about $3 million in sales. And we reported $15 million sales in the - in the third quarter.

Correspondingly, on the next slide is the operating income. You can look at the leverage the company gets as the sales grow (ph). We reported $3 million in net income in the - in the third quarter.

On the - on the next slide is the capitalization. We currently have 11.5 million shares - approximately 11.5 million shares outstanding. There is a private placement that was completed in August of 2001. And that converts into a fixed number of shares, which is about 3.6 million shares.

Employee options and warrants (ph) are approximately 2.7 million. And these range in price from a low of about $4 to share to a high of $8.30 cents per share. That's with (ph) employee fall in that range.

If you take the totals, there's approximately 17.8 million - potential for 17.8 million shares to be outstanding at the end of the day. However, if you (ph) use the treasury method, that number goes down in (ph) the third quarter and could be -

could be obviously different now. But it's a range of approximately 17 million total shares outstanding.

Let's talk a little bit about our manufacturing facilities.

We have 110,000 square-foot facility. This is divided into four different buildings. Our main manufacturing building is 46,000 square feet. We have recently doubled our manufacturing capacity by adding additional equipment, like the blenders; packaging lines, compression machines, et cetera. We have invested over $5 million in both the manufacturing and the - and the lab equipment. We are licensed to store (ph) and work in all classes of controlled substances.

And what we believe, looking at the pipeline, and our current portfolio - that the capacity we have right now is scalable for about 18 months. After 18 months, we would need to add additional manufacturing capacity. If we need to, we can always add warehousing space or office space. But manufacturing capacity wise, we believe 18 months is a window, after which we'll need to review the manufacturing (ph) space.

Let's talk about the regulatory status on the next slide.

We have had about five or six inspections in the last two years. The last three inspections took place within six months - the last six months. All of them were clean. There were no observations that were given to us by the FDA. And no form 483 (ph), which contains those observations, was issued to us.

Our track record with the FDA, as we discussed earlier, is pretty good. We received one approval within five and a half months from the time of filing. Our average is running about nine to 10 months.

Able Labs' main facility used to be under a consent decree (ph) that was entered by previous ownership in going back to 1992. And in February, we were able to have that consent decree (ph) removed. And we're very proud of the fact that we were able to show the FDA the level of quality that we have in the operation. And the FDA recommended to possess this (ph) department of a fall to (ph) consent decree (ph). And that was removed as well.

And finally, we want to talk a little bit about the 2002 milestones.

We have given the guidances (ph) for Q4. As you know, we do not give number guidance, or we do not give any quantitative numbers. What we have said in the last conference call - and this is what I would repeat - is barring any unforeseen (ph) circumstances, we will - we will see increased sales, obviously increased R&D expenses, and corresponding net income increase as well in Q4. Some of the milestones for this year which we have achieved - we had filed for NASDAQ re-listing. As you know, we were a bulletin board stock. We received a NASDAQ listing.

We were in the process of completing the senior management team. We have been saying that for the last six months. And with the addition of new VP of Sales, VP of Corporate Development, and now the Chief Financial Officer, we believe we have rounded out our management team very well. We continue to have quite a - quite a pipeline spending (ph) at the - at the (INAUDIBLE) as well.

And that brings us to the last slide. And this is a repeat of what you've seen. But I'll leave you with this thought about what the investment highlights are for Able, which include a (ph) rapid expansion base, customer base, growing margins, niche product opportunities, an aggressive R&D program, a good track record with the FDA, net operating losses available for offsetting tax payments for the foreseeable future, and an excellent management team.

So with that, we will ask the moderators to take questions.

QUESTIONS AND ANSWERS

Jim Flanagan - *IR Strategic Advisors - President*

Thank you, Mr. Wadekar.

We've been listening to the presentation of Able Laboratories.

I (ph) want to remind our live Webcast participants that you may submit a question at any time by simply typing your query into the question field that you'll find on the lower left-hand side of the Webcast player.

Our first question

Mr. Wadekar, who are your largest customers?

Jay Wadekar - *Able Laboratories - President and CEO*

Well, we currently have - I would say some of the wholesalers are currently our largest customers. These are major wholesalers,

followed by national chains such as CVS (ph), Walgreen's, Rite Aid, et cetera.

We don't break down our quarter-to-quarter sales. We do that once a year at the end of the year. But as of last 10-K, Cardinal Healthcare (ph) was one of the largest customers for the company.

Jim Flanagan - *IR Strategic Advisors - President*

Great.

And regarding your capabilities to formulate tablets, capsules, et cetera, what do you consider to be your core capabilities in this area?

Jay Wadekar - *Able Laboratories - President and CEO*

I think modified-release or (ph) sustained-release formulations, some of the difficult-to-match tablets, as well as capsules - I think that is the core competency. We obviously - we do not operate in the creams, liquids or injectibles.

So (ph) our core competency is these three areas.

Jim Flanagan - *IR Strategic Advisors - President*

In the introduction of the company, we talked about Able having received 21 abbreviated new drug applications since March of 2001. And in your presentation, you talked about a very active pipeline at the FDA.

Can you - can you give us any idea of number of additional (ph) application approvals that you might think would be the appropriate number, on a year-to-year type basis?

Jay Wadekar - *Able Laboratories - President and CEO*

Well, as we said, we're going to target about 15 to 20 new drugs for the - for the year 2003. I heard the previous presentation. It's very difficult to really predict the timing of either the filing or the approvals. More the approval; as you know, the FDA cannot - we cannot predict what FDA's time line would be.

But having said that, we do expect what we have on file to certainly come through (ph) in the year 2003. And hopefully, some of the early filings we'll be doing in 2003 could be approved by the end of the year as well.

Jim Flanagan - *IR Strategic Advisors - President*

And relative to the approval, that results in increase in manufacturing. How's your manufacturing capacity? And will you need to fund any additional capital for manufacturing?

Jay Wadekar - *Able Laboratories - President and CEO*

We would need some additional capital. And I believe at the last conference call, we had said that about $500,000 to $800,000 more would need to be invested in capacity expansion.

But with that, we expect that whatever we have in the pipeline currently, as well as what we get approval on over the next 18 months - we'll be able to manage the production in the current area - in the current building.

Jim Flanagan - *IR Strategic Advisors - President*

You talked about the difficulty of predicting FDA approval. And that's not uncommon for any company. But what is typical that you're seeing for the receipt of (ph) approval for FDA for, say, a generic drug?

Jay Wadekar - *Able Laboratories - President and CEO*

Our average has been about nine months. And unless there is an issue with the - with the active drug manufacturer from whom we source the product - or sometimes it could be delays in the - in some of the suppliers not getting compliant with the FDA - those are all unfortunate circumstances; they're (ph) beyond our control as well.

But assuming that there is no delay by any of these outside factors, our average approval rates are running between nine and 10 months.

Jim Flanagan - *IR Strategic Advisors - President*

Great, appreciate that.

Remind our Webcast participants that if you're participating live today, you may submit a question at any time by simply typing your query into the question field that you'll find in the lower left-hand side of the Webcast player.

Our next question is relative to your comment earlier in your presentation about increasing gross margins. Is there a typical gross margin that you think that would be representative for your company going forward?

Jay Wadekar - *Able Laboratories - President and CEO*

Well, we have been - we've been seeing about 47, 48 percent gross margin; in that - in that range.

What we would expect to - expect to see going forward - some of these niche products give us higher-than-average margins. But obviously, the sales are not very high on those. And that is offset by some of the price (INAUDIBLE) you see in the market as well.

So it's an offsetting - it's an offsetting effect. However, it does maintain the company at a very healthy total gross margin going forward.

Jim Flanagan - *IR Strategic Advisors - President*

Good (ph).

Our next question is about the management team you've noted in your presentation. A bucketed (ph) team that you're looking to fill out at this point in time? Or do you feel that you've got the key capabilities in the company at this point in time?

Jay Wadekar - *Able Laboratories - President and CEO*

Well (ph), we continue to look for very high-quality research and development people that can - that can bring expertise and increase their R&D - success with the (ph) R&D program.

And we also keep looking for very seasoned sales professionals, very high-level salespeople, that can bring in - bring the relationship and their understanding of the - of the business. With each of the additional salesperson we bring in, we expect to increase the sales pretty significantly, too.

So those are - those are areas we really like to invest in. Because they translate into very positive things for the company in short term.

Jim Flanagan - *IR Strategic Advisors - President*

Transitioning from the comment you made about sales professionals - what are seeing in pricing trends in your products and in the marketplace (ph) right now?

Jay Wadekar - *Able Laboratories - President and CEO*

A few of our products have experienced some downward pressure in the price. However, we had never priced it so high that we have to take a rapid (ph) decline in the price.

We're seeing - we're seeing our prices being affected less than maybe our competition's at this point. However, there is - there is a slight decline in the - in some of the pricing.

Jim Flanagan - *IR Strategic Advisors - President*

Do you expect that to continue?

Jay Wadekar - *Able Laboratories - President and CEO*

Doesn't continue forever, obviously. Because, you know, you'd (ph) start to lose money in the end. It does stop.

But we - internally, we expect - on an - on an across-the-board basis, about two to three percent decline in pricing, quarter over quarter. And then it levels off at the - at the (ph) very competitive levels before it starts to move back up.

And so it's a very dynamic process in pricing.

Jim Flanagan - *IR Strategic Advisors - President*

We have a follow-on question from one of our Web (ph) participants, asking if you foresee any additional approvals this calendar year.

Jay Wadekar - *Able Laboratories - President and CEO*

It's hard to say. We would like to see some. I think we're (ph) due to get some. But we're getting into the - into the holiday season. And the FDA is no different than any other operation, where they'll have vacations, et cetera.

However, we have seen a little bit of increased activity in the approvals of the - from the FDA in the last couple of weeks. Hopefully, we get one or two more approvals by the end of the

- end of the year. But again, that's speculation on my part. It could be beginning of next year as well.

But we certainly have a few pending that we should be getting any time.

Jim Flanagan - *IR Strategic Advisors - President*

Our next question is relative to common practice in pharmaceutical companies and companies in the life science area, of partnering with other companies. How does (ph) strategic partnerships - how are they (ph) looked at in your company?

Jay Wadekar - *Able Laboratories - President and CEO*

Well, right now, we've been able to do a pretty good job penetrating the customer base. For us, strategic partnership would be necessary in one of the two areas: number one would be technology; and number two, potential market penetration into some of the significant customer base.

We've been able to do both on our own. And therefore, there is no immediate plan to look for any of those opportunities right now. Can't predict what could happen in the future.

But right now, we don't see anything happening immediately.

Jim Flanagan - *IR Strategic Advisors - President*

We'd like to ask the companies presenting that they look forward. What are the - for the investors, what are the key milestones that they should look at as proof points that you're on track to achieve your goals and objectives?

Jay Wadekar - *Able Laboratories - President and CEO*

Well, our story is pretty straightforward. The more you will see - you will continue to see filings, FDA filings. And each quarter, when we do our 10-Qs in the case (ph), you will see the number of approvals pending, and also the approvals we get. I think those are the two areas - two key areas for the company.

In addition to that, bringing on some sales trend (ph) marketing professionals - that should - that should give us more exposure as well, in getting into more accounts.

So those are - I think those are the three areas that you should be looking at.

Jim Flanagan - *IR Strategic Advisors - President*

We've been listening to the presentation of Able Laboratories, and Mr. Jay Wadekar, President and CEO.

We have no more questions at this point in time, Mr. Wadekar.

We'd like to thank you and your company for presenting in today's CCBN's Virtual Healthcare conference.

For our online Web participants, we'd like to let you know that this completes this section of our broadcast presentations today.

Thank you for participating in CCBN's Virtual Healthcare conference cosponsored by Lippert/Heilshorn and RedChip Partners. Thank you.
