FINAL TRANSCRIPT

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Event Transcript

LFP - CCBN Virtual Healthcare Conference: Co-sponsored by Lippert/Heilshorn & Associates and RedChip Partners

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CORPORATE PARTICIPANTS

Peter Hall
CCBN - Senior Vice President

CONFERENCE CALL PARTICIPANTS

Linda Masterson

PRESENTATION

Peter Hall - *CCBN - Senior Vice President*

Welcome to CCBN's Virtual Healthcare Conference, co-sponsored by RedChip Partners and Lippert/Heilshorn & Associates.

My name is Peter Hall and I'm a Senior Vice President here at CCBN. And I'll be serving as your moderator for this portion of our virtual healthcare conference.

I'd like to remind our live listening Webcast participants that if you would like to submit a question, you can simply do so by typing your query into the question field in the lower left-hand side of the Webcast player.

I'll present these questions during the Q&A at the end of the company's prepared remarks. Should I have more questions than time allows, please be sure that we will forward all questions to company management for them to respond to it directly.

The following presentation is by LifePoint, Inc., ticker symbol LFP. LifePoint, Inc. is a fully reporting medical products company that has patented proprietary platform technologies for the medical diagnostic testing industry.

The company's mission is to become the market leader in noninvasive, saliva-based, on-site, cost-effective rapid diagnostic products.

Representing LifePoint today is Linda Masterson, Chairman. Miss Masterson, you may begin your presentation now.

Linda Masterson

LifePoint has developed and is now marketing a very unique product. For the first time, by sipping (ph) a few drops of saliva into a small disposable cassette used in conjunction with a portable instrument, we can generate up to 10 blood-equivalent results in under five minutes.

Saliva is made from blood plasma. So most of the molecules that are found in your saliva are also found -- that are found in blood plasma are also found in saliva.

And so, if you can accurately and quantitatively measure those elements in saliva, along with certain characteristics of the saliva as it's collected, you can generate blood-equivalent results.

LifePoint has developed a very automated and intuitive-to-use instrument that automatically checks itself to ensure that you get a correct answer.

And so, for the first time, EMTs and paramedics would be able to get immediate life-saving information. Or a home healthcare nurse would be able to affect treatment rather than taking blood plasma and coming -- a blood sample and getting a blood result a couple of days later and having a repeat visit. And even consumers will be able to, for the first time, self-test.

We believe that LifePoint has all of the key ingredients of a very successful investment. First and foremost, all of the senior managers have at least 25 years proven experience in their respective areas.

More importantly, the first product that we selected, the simultaneous detection of drugs for abuse in alcohol, has 11 target markets. It's not only unusual for a single product to have a couple of markets, but to have 11 is both a marketer's nightmare and dream all wrapped up in one.

The first three markets that we're focused on are law enforcement for driving under the influence of drugs, the industrial workplace and the medical emergency room for overdose testing. Those three markets represent a $1.6 billion market opportunity with no current direct competition.

Additionally, all of those initial markets have high unmet needs. We have, using the classic razor/razor (ph) blade business model, the small repeat disposable generates a recurring model. And one year out, it is expected to have 70 to 80 percent margins on that.

The company has a very strong intellectual property position. We have over 20 patents that are issued or pending. And one of the reasons that we selected the simultaneous detection of drugs and abuse in alcohol was that several of the initial markets are not regulated by the FDA.

So as a medical company, we did not have a regulatory risk that was dependent on FDA approval. And subsequent to initiating

the development, we now know that this is a simple 510(k) and our product is currently pending FDA approval.

The company is located in Southern California. We have two facilities, a 32,000 square foot manufacturing facility and corporate headquarters, as well as 10,000 square feet in an R&D facility a couple of miles down the road.

Our manufacturing strategy is very straightforward. Since two years out, the disposable represents a significant portion of our sales and profitability. That is an -- it also represents our core competencies. That is an area that we will continue to focus on, on a go-forward basis to not only continue developing additional menu products but also to manufacture on an ongoing basis.

Alternatively, the instrument, which represents not a significant portion of the sales opportunity for the company, ultimately will be OEMed to a manufacturer who has already been selected and that has core competencies in the area of low cost and reliable quality manufacturing production for a similar type instrumented system. Next slide.

The LifePoint product works very simply. The size of the instrument is approximately the footprint of a laptop. The keyboard you see in the picture is actually one of these very small keyboards to give it a size correlation.

There are (ph) three steps that the operator performs. You hit a start button, which basically like an ATM, the messages change on the four function keys. And an arm will come out. You then take the disposable cassette and insert it on the arm and hit the start button again and (ph) which it retracts.

The only other thing the operator does is, as you can see on the keyboard, there's a mouthpiece that's similar to a dental aspirator. You uncap that and that is placed into the donor's mouth.

You hit the start button for the third time and the instrument starts to vacuum a sample out of the person's mouth directly into the disposable cassette.

It takes approximately 30 seconds for a sample to be collected, at which point in time, the instrument, after it measures the collection will indicate to the operator that the specimen collection is adequate.

And you will then take the mouthpiece out of the person's mouth and recap it. At that point in time, the instrument automatically controls the rest of the process.

It will process the saliva sample, distribute it in up to 10 different testing channels, cause the reaction to occur, read the results, interpret that signal result against a 2D (ph) bar code that has a standard curve that is designated by the manufacturer per analyte and per lot number and interpret that information to give you a result.

It will then print that result on a screen, along with a printout. That entire process takes less than five minutes.

Therefore, we have developed a product that is completely automated and intuitive to use and virtually can allow testing by anyone, anywhere, at any time.

There's really two core technologies that have enabled the development of this unique product. The first is, for the first time, a highly sensitive, quantitative, detection method that is very fast.

The reaction occurs in a few seconds. And it's very simple to use. The format is a single reagent. So it was incorporatable into a single simple format type test product.

This technology combined the accuracy we'd normally get out of a lab-based system, which will give you highly sensitive and quantitative results but would normally take multiple washing (ph) steps, reagents, sophisticated equipment, highly trained personnel and several hours to accomplish.

Alternatively, there are simple lateral flow membrane (ph) technologies similar to pregnancy tests that can generate a fairly rapid answer. But those technologies generate a level of sensitivity that is several orders of magnitude less sensitive than the current lab-based systems and only will give you a yes/no answer.

LifePoint's flow immunosensor technology was originally developed by the U.S. Navy, first used for air sniffing for chemical warfare agents in Desert Storm and was used for anthrax detection. And it's that technology that combined the two benefits.

For the first time, in a few seconds, we can generate a lab -- a lab quality result with sensitivity that's actually greater than the current lab-based systems by several orders of magnitude and was easily incorporatable into a simple format product.

The second technology is the use in processing of saliva to give a blood comparable result. By the mid-'90s, there was a lot of information about the usefulness of saliva as a diagnostic tool.

But in order to generate that information, one not only has to be able to collect the saliva in such a way as to generate that quantitative information but also to test for certain elements of the saliva as it's collected.

It was the first technology that was developed by the U.S. Navy that led us to believe that we could finally capture that information from saliva. So by being able to quickly and easily and quantitatively measure the elements in saliva, along with certain characteristics, we're able to generate that blood-equivalent result.

We decided to use aspiration as the method of collection. There's really three ways you can collect a saliva sample. You can expectorate, which is not considered market acceptable.

You can use absorption methods, which is typically what's being used for saliva collection for transport to a laboratory and has been used successfully in analyte detection when there are very high levels of the analyte available in saliva, so for example, HIV antibody detection.

It has not been successfully used for say drug detection where the levels of sensitivity have not been validated.

We have two patents that have issued in this area, one for the unique collection utilizing aspiration. The advantages of that is that you have a very rapid and controlled collection. The average collection is about 30 seconds. And also, we're able to measure and quantitatively collect the sample as it's collected.

The second patent allows for the detection and measurement of saliva and to be able to generate that blood-equivalent results.

Both of those patents have issued in the United States. And there are worldwide patents pending.

If you look at this next slide, you'll see a diagram of how the product works within the test cassette itself. As you can see, there is a saliva that's collected from a person. It goes into a sample collection chamber. The instrument measures the collection as it's collected until enough of the sample has been collected.

At that point in time, the instrument will indicate to the operator to quit the collection and the vacuum goes off. The saliva sample is then mixed with a buffer sample and distributed in up to 10 different testing channels.

By changing the columns and the mix of columns in any test cassette, the -- we can change the use of each cassette. The sample then flows through that reagent chamber.

If a reaction occurs, a fluorescent signal will flow downstream of the reaction chamber and will be read by a laser that is reading fluorescents and the strength of that signal is compared to a 2D (ph) bar code and the result interpreted.

The sample and the buffer go into a waste chamber which is self contained. So nothing ever leaves the cassette and does not interact with the instrument in any way, shape or form. So it's a completely self contained, a simple disposable method.

As I mentioned earlier, the first product that we selected for development was drug and alcohol detection for the reasons given previously.

Longer term, we will continue to stay focused on drugs. The reason for that is the area of saliva correlation with blood levels in drugs is exceedingly well validated.

So not only for illicit drugs but also for therapeutic drugs, the ability to get noninvasive information that will give you a blood-equivalent level that can be acted on is very well validated. And we as a small company did not have to go out and validate the biophysiology of that.

Long term, we see LifePoint's opportunity in any market where either immediately collected information that's noninvasively obtained can either save money in cost of healthcare delivery such as long-term care, wellness screening, self testing, home healthcare or where it can literally save lives, such as first responders such as EMTs, paramedics, medical emergency, et cetera.

The first market that we've already launched into is for law enforcement for DUI testing. The data is actually quite compelling. The first initiative for DUI for drugs really came out of Europe.

There was an EU-funded study that showed that driving under the influence of drugs represented between 6t and 85 percent of the DUI problem in the countries that participated in the study.

They then went on in that study to look at potential protocols that could be used to try to be able to generate drug information as easily as currently is done with alcohol breath tests.

And what they found is that there was no current easy available methods. And they define the ideal product as an instrumented saliva-based panel test with results in under five minutes.

Because of this, there's been a huge demand for the product, especially from overseas and Western Europe. And we have countries that are literally lined up and waiting for this or in progress of doing evaluations. Currently 10 nations are looking at our product.

More recently, about two weeks ago, the White House, in conjunction with the Office of National Policy has indicated a similar initiative in the United States. And they now have described December as the drug driver prevention and awareness month.

And we believe that this is great news for LifePoint and will now start to accelerate the same kind of visibility that we currently have in outside of the U.S., especially in Western Europe to the United States.

What currently happens now is that an officer will typically pull you over for cause. You'll be weaving or speeding. They'll then ask you to do some -- to subject yourself to a field sobriety test. That's when you walk the line, stand on one leg, touch your nose, et cetera, and you're graded on that.

If you fail the field sobriety test, basically, you're considered impaired. And they have probably cause to go on and do further testing.

The first test that would normally be done would be an alcohol test. If they do the simple screening tests that are done at the roadside, those are not normally admissible in a court of law. So they then would normally take the person back to the police station and do an evidential breath alcohol test.

If that is now negative, they would then take the person to a medical emergency room, get a blood draw, send that sample under (ph) chain (ph) of custody to a criminal forensic lab.

And somewhere between a cost of 60 and $250 and between two weeks and two months later, they'll get that result back. Our product would give them immediate result for drugs and alcohol at the police station for a cost of 35 -- $30.

So not only is it directly cost beneficial but it will -- it's also operationally efficient in that you don't have two officers taking someone to a medical emergency room and waiting an average of four hours for that blood draw in the United States. We've had a huge amount of interest even out of the U.S. law enforcement agencies.

The second market is the industrial workplace. This actually is a huge market and fairly uniquely a U.S. market, unlike the other markets that we're focused on. Last year, over 41 million tests were done. And this is a huge problem.

We originally focused on that portion of the industrial workplace that had the same requirements as drivers. Basically saliva and blood are giving you an under-the-influence indication. It will give you a positive test while the active parent drug is in the person's bloodstream.

We originally focused on the current worker testing, which is basically the post-accident random and reasonable suspicion market, which has the same requirement to get that under-the-influence result.

Interestingly, more recent data that has been generated shows that the -- in the pre-employment portion of the market that there is now a huge opportunity for LifePoint.

Currently, pre-employment drug testing is done mostly by tests. Urine tests give you different information than saliva or blood. Urine will show drug use over the last two to five days. But it will take several hours for it to turn positive in your urine.

One of the problems with urine testing is that basically you have a lot of cross re-activities (ph). A classic example is poppy seeds and opioids because you're testing for the metabolite rather than for the active parent drug.

So by using either saliva or blood, you get an increased level of specificity over the current urine test method. But urine because it's easily collected has become the defacto standard for simple pre-employment screening testing. Some studies that were done that compared urine tests to saliva tests for pre-employment had interesting results.

Although you would intuitively believe that a two to five-day drug test is going to give you more positives than a one-day drug test, what they found was that the saliva gave about the same number of positives in some drugs and in other drugs actually more positives.

And this became evident that this was an effective way to prevent the current problems with urine substitution and adulteration of samples. There's been a huge effort to try to beat the drug test.

And there's a lot of Web sites that sell products that will either sell you clean urine so you can substitute someone else's clean urine for your dirty urine or chemicals that can be added to the urine in the cup after it's collected.

And since urine collection is not generally observable, these have been fairly easy to implement. Saliva, on the other hand, which is observable, eliminates the ability to do that.

And because of that, SAMHSA, which is the federal government agency that regulates the process by which federal safety sensitive employees are tested -- hey don't regulate the products but the process -- has added saliva testing not only for post-accident, random and reasonable suspicion but also pre-employment, which has opened up the entire market for us.

Our customer in this marketplace is either the employer themselves who, for the first time with a quantitative, legally admissible results and a legally defensible result feels more comfortable in utilizing the product themselves and also because employee A can't impact the results on employee B.

And alternatively, the service providers who would be able to give both the drug and alcohol results right away rather than just giving the alcohol result and waiting several days for the urine drug test result, they'd be able to give them both.

And this is both a profit and revenue generator. We actually believe that this market, which will be the next one that we launch into, will be among the fastest to move markets.

The third market that we'll be focused on is the medical emergency market. This does require FDA approval. And our product is currently pending 510(k) approval.

Basically in this market, there are less than 100 hospitals that have the ability to do a drug blood overdose. It requires the ability to have a very sophisticated instrument called a gas chromatograph mass spectrum photometer (ph), which is very difficult. And even if one is found, it's three hours off to the first result.

So basically, most overdose victims are treated empirically. So literally, our product will, for the first time, give emergency room physicians the ability to detect specifically what drug someone has overdosed on and more importantly by what amount so that they can match antidote levels to overdose levels.

Basically we believe that this market will also move very quickly, especially (INAUDIBLE) which we're in the process of doing our submissions for right now, which allow non-technical, non-laboratory regulation for the product even in medical environments.

The next slide shows a breakout of the markets at a very high level. We have significantly detailed information on our Web site under investor information, if you would like to know where and how all this data is generated, along with all the third party references.

But this market in 2000 represents -- 2002 represents approximately a $1.6 billion market opportunity in the United States and Western Europe.

Our sales and distribution strategy has been very straightforward. In the law enforcement market, we have a strategic partner, CMI Incorporated. They have the -- they are the market and technology leader in breath alcohol testing. They have the 80-percent market share in the United States and market to 60 counties on a worldwide basis.

They have the direct sales feet on the street, a proven after sales product support group, quality reputation and access to the people that we felt really were the decision makers in the United States.

More importantly, we felt that they could really accelerate our penetration into this market. They're working with us on a strategic basis and basically, our sales and marketing arm.

In the industrial workplace, we plan on using a matrix approach (ph). For the very large employers and service providers, we'll be using our direct key account sales reps, which will actually call on the service providers or the employers themselves.

And then, for smaller employers and service providers, a distribution, typically health and safety distributors, we typically call on both the employers and/or the service providers in that market.

The medical market represents our first totally direct sales effort. Basically, although there are 6,600 hospitals in the United States, about 950 do about 90 percent of the testing. So a small sales and marketing group can really penetrate down into this market. And as I said earlier, we currently are focused on international mostly through distributors.

Our pricing strategy is very straightforward. For the disposable cassette, $30 versus 250 to 500 for a blood drug test. To put that into perspective, four things will generally sell a product. Either

customers will buy every product or service because it's either faster, easier, better or cheaper or some combination.

Against a blood drug level where you're talking about a GCMS (ph), LifePoint brings all of those elements and it significantly has a significant, compelling selling story.

In the industrial workplace for the pre-employment test portion of the market only, we're competing with a urine lab test, which is about 95 percent of the market. And we've priced that $30 against that.

On the instrument, our price will be about 12,500 to the end user. That compares with a breath alcohol -- evidential breath alcohol test of between five and 8,000 and a clinical analyzer of 15 to 30.

Depending on the market, we'll be utilizing different financial approaches. In those markets with distribution, obviously we will be selling our product to the distributor, who will then be reselling it under some of these programs to their end customer.

Competitively, the company is in a fairly unique position. There's no products that can test simultaneously for drugs or alcohol. And there's no test that can provide an on-site, quantitative level for drugs under any circumstance.

As I said earlier, in the driving-under-the-influence market for drivers, the industrial workplace for current employee testing and for the medical emergency room, the current methodology of use is a blood drug level. And basically we bring significant advantages to each of those.

For the pre-employment market, we're competing with the urine lab-based test. And we're at price parity but basically bring the other three advantages of faster, easier and better.

So if you look at the next slide and you look at the overview of the different markets and what customers are looking for, you can get a sense of what the IMPACT Test System brings versus all the other methodologies for drug and alcohol testing.

The company has put itself into a position to be able to move forward commercially. We've launched into our -- into the market. We have been able to achieve the financing we've needed. The company has acquired the and (ph) been able to hire and retain the senior management it needs to be able to effectively reach our goals.

And basically, we have already completed our 510(k) submissions for the core submission so that we will be able to start marketing into the medical markets as soon as we have approval. So what we can expect for milestones over the next 12 months is pretty straightforward.

We will be shortly initiating our launch into the workplace. And basically, once that's done, we will then be looking for 510(k) approval to initiate and launch into the medical markets.

Over the next year, there will be a significant effort by the company not only to leverage our sales as we will be doing with efforts into the additional markets but also to ensure that our production capacity is maintained and that we continue to reduce our cost to make sure we achieve profitability. These will be all focuses of the company over the next year.

The next two slides show very briefly an overview of the senior management and the experience level of the different managers. The next slide shows a fairly traditional scientific advisory board and consultants.

What's a little bit unusual for the company are the next two slides, which show the substance abuse advisory board, which is essentially a marketing board.

These consultants or people that are working with the company are highly affiliated in those other eight markets that we'll begin to focus on over the next year.

This includes everything for schools to military to substance abuse prevention and treatment, as well as insurance testing, et cetera. And these people can help us achieve both our strategic and tactical goals in these areas.

The last slide is our financial overview. Basically our last reported financials are at the end of September. At that point in time, we had reported revenues of just under $200,000, cash of about 2.1 million, but (ph) total assets of 10.1 million, which included inventory level of 4.5 million.

The inventory got a little bit out of hand and a little bit ahead of itself. But the good news is that we'll actually be able to sell that down without having to reinvest in inventory.

Our running rate at this point in time was about $1.1 million a month. But we've now significantly lowered that, one, because we have no longer the need for a lot of the engineering services that we were using in order to get to profitability and we're also

in a position now where we're not having to invest money in additional inventory.

On the capital side, the company basically has 36 million shares outstanding, many of them in the public float. We've been trading between 1.50 and 2.50. And our volume actually is up from what's listed on here. It's probably closer to about 100,000 a day as we are through (ph) the end of this particular quarter.

I now open for any Q&A.

Peter Hall - *CCBN - Senior Vice President*

Linda, we really only have time for maybe one or two questions. Let me ask one question. Do you have any really -- any major customers yet of your product? And if so, what's the feedback? And do you envision any announcement about a major contract in the future?

Linda Masterson

The company is in significant evaluations both inside the U.S. and outside of the U.S. for, in many cases, fairly substantial customers, which essentially are nations. Those evaluations are still ongoing.

We have not made any announcements at this point in time. But we will for any material sales contract that would be significant to the company. So when those occur, we will be making those announcements. We do not have any as of yet.

We're now starting to run into the end of the year where a lot of studies will probably start to slowdown because of reduced staffing through the holiday period of time as people take off, especially in Europe. It tends to actually be more problematic over there.

QUESTIONS AND ANSWERS

Peter Hall - *CCBN - Senior Vice President*

OK. Linda, I want to thank you very much for your presentation. And there are some additional questions that we will -- e-mail questions that we will forward on to you.

Linda Masterson

We'll be more than happy to respond to all of them and send them back to you.

Peter Hall - *CCBN - Senior Vice President*

Thank you so much for your presentation.

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