August Investor Perspectives Show # 2
Impact of COVID-19 on Chronic Pain Market
Featuring Brian Carrico

COVID-19's Impact on the Chronic Pain Market

In today's show, you'll hear investor perspectives on the COVID-19 impact on the chronic pain market.

This is Investor Perspectives, I'm the host of Investor Connect, Hall T Martin, where we connect startups and investors for funding.

It's the time of COVID-19. The healthcare industry is overwhelmed with patients from the pandemic. Medical conditions such as chronic pain continue to grow due to the opioid crisis.

We recently held an interview with experts and investors in the area of chronic pain. Our host is Ashley Matthysse.

Our featured guests are:

Brian Carrico, CEO with Innovative Health Solutions: https://i-h-s.com
Michio Painter, Pain Specialist, Investor with Joyance Partners:
ww.bluetherapeutics.com; www.joyancepartners.com
Steve Shapiro, Partner eHealthVentures: www.ehealthventures.com

I hope you enjoy this episode.

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Intro

We recently held an interview with experts and investors in the area of Chronic Pain. Our host is Ashley Matthysse.

Ashley Matthysse (03:41):

Thank you everybody for joining today. My name is Ashley Matthysse, I am the Director of Outreach for TEN Capital. I am joined today by some lovely gentlemen, thank you so much for being here. Michio Painter is a pain specialist and investor with Joyance Partners, Brett Lanuti is with Nocimed, Brian Carrico and Dan Clarence are with Innovative Health Solutions. This discussion on Investments in Healthtech and Treatments of Chronic Pain is meant to be as informative as possible. Michio, I would love to start off with your background and experience in pain management and healthtech, if you want to kick us off.

Michio Painter (06:35):

Thanks everyone. I'm Michio Painter and I'm a venture partner with Social Starts in Joyance where we invest in what we call the deep science of health and happiness and delightful moments and certainly healthtech and chronic pain is part of that. That's a particularly important topic to me because I'm also the founder of a company called Blue Therapeutics, where I've been the CEO there for the last five years trying to develop non-addictive painkillers, so I've kind of been on both sides of the table if you will. From an investor point of view, I think it is really an exciting area because if you look at it, pain as a whole, I think, has the largest discrepancy between its kind of unmet need, the number of patients that are in pain have various forms of pain, the healthcare burden in terms of the financial cost to society, and a gap in lack of funding. So, actually it's an area that I think is just very primed for new solutions across the board, and I think that extends well beyond the - kind of - opioid crisis that we're all familiar with by now. I think the problem of pain goes back many decades before that, where we just have not had good solutions. We've had sort of broad, not terribly effective strategies, but I think now, you know, we really need to develop better precision in our therapeutics, whether that's treatment for specifically for women in pain, making much better and more rigorous non-drug approaches towards pain is another thing that you're going to hear about, and also there's a huge need for just better diagnostics and _____ here's because right now we're relying heavily on just patients' feelings of things, which is always hard. So, in short, I think that I'm very excited as an investor by the space, I've helped to lead an investment personally recently in pain, and I'm excited to hear more from these two companies. So, thank you.

Ashley Matthysse (14:29):

Brian and Dan are here with Innovative Health Solutions or IHS. Gentlemen, thank you for joining today. If you want to go ahead and give us your update with IHS.

Brian Carrico (14:54):

Thank you for having me. So, my name is Brian Carrico. I am the CEO of Innovative Health Solutions. We have been in business since 2011, we really have been working on the research since 2014 and what we are is we've developed the first and only in the world, FDA-indicated technology to get to the central nervous system without a pharmacological pharmaceutical, or without a surgically implanted device. So in 2014, we proved that we were doing neuromodulation, getting to the brain and spinal cord to the

central nervous system, and in 2015, we began our first randomized control trial in children with functional abdominal pain associated with IBS. This past summer we received our first indication in pediatrics, we really are a pediatric company. Our pipeline consists of, we just got the functional abdominal pain in children associated with IBS, and then we have functional nausea in children that will be done this November. Following that, that's at Children's Hospital, Wisconsin, we've got a post-concussion study at Children's Hospital of Orange County. We've got a COVID study going on at UCLA to reduce inflammatory markers, to reduce inflammation in the lungs, get people off of ventilators and out of the hospital center, and we've got the adult version of functional abdominal pain started now at UCLA. The final pediatric indication we have is for chemotherapy-induced nausea and vomiting in children, and that's being done at Children's Hospital of Wisconsin. So, we've got essentially, seven double-blind placebo-controlled trials in place. One of those seven is now completed, and that is the functional abdominal pain and that is the technology, that is the indication we are in the process of commercializing right now. We launched that technology in January, we actually hit profitability the first month, and I believe as the other gentleman said a second ago, we actually were profitable in March as well, and March 17th when COVID hit, we lost roughly eight weeks of revenue and we didn't think we'd get revenue back until July, we actually came relatively close to profit in May and June, and we're doing a $17 million Series A right now. We just had $8 million invested in April by a $13 billion med-tech company called Masimo, we also licensed our initial indication about three years ago in the opioid withdrawal space to Masimo, and so, right now we're sitting on about $4 million in cash, we're going to raise this additional five and a half million dollars, which will give us roughly nine, nine and a half million dollars and we're sitting right at profitability. So you might say, well, why are you raising this money? And it's really pretty straight forward. We've got additional indications coming, mostly pediatric, but a couple of adult indications that we will need to hire additional salespeople for, hire additional market access and reimbursement people for, and additional clinical staff for, and we don't want to be in a position where we can't scale fast enough to meet the demand of the market. We've got eight of the top 10 children's hospitals in the country currently using the technology. We believe we're on pace to hit right at $3 million in revenue this year, we'll do right at $10 to $12 (million) next year - I think we can do better than that - we'll do at least $10 million next year, and the goal is to double the next three years, $10 million, $20 million, $40 million, and at that point we believe, based on our conversations with some of the strategics that have contacted us - a very large strategic in the medical device space, in the pharmaceutical space - is we can do a 10-12X multiple. The pre-money valuation on this is $35 million on this Series A, on this remaining five and a half million dollars, and we're hoping, expecting to get these revenues to $30, $40, $50 million in the next three years, three to four years, and be able to exit a 10 to 12 multiple. We're sitting in a position where we only go after indications, which A, we have pilot/anecdotal data, number one. Number two, it meets the scientific pathway, makes sense with our science, which is basically around the amygdala, which controls pain, fear and anxiety. And number three, we have little to no competition. Our first indication which I'm referencing, is in functional abdominal pain in children. You have 6.2 million children in the country that are suffering from this, roughly 3 million children currently do not get better from any diet modification or lifestyle changes, so we've got about 3 million patients as our target opportunity and there's no competition. There is no other FDA-indicated drug or device for these children, there's nothing else in Clinicaltrials.gov coming behind us in the coming few years, not to mention our very strong IP portfolio, not only with the device, but with the method patents. So, that's a very high level 30,000-foot view of who we are as a pediatric company, the commercialization, our revenues, and the Series A along with our exit strategy.

Ashley Matthysse (19:51):

You briefly mentioned insurance, can you talk about insurance coverage for the IB _____?

Brian Carrico (19:59):

Well insurance is - as anyone in med-tech or pharmaceutical for that matter understands - insurance is the difference between us doing $3 million next year or $30 million or $40 million or $50 million in three or four years. Currently we're on what's called a Treat First Program with the children's hospitals, where they treat the patient then they bill insurance, and then if they get reimbursed, they pay us, if they don't, they don't, we write it off. We're at about an 88% Treat First success rate right now, which is incredible. We think that's partially because these children have no other option. Number two, they are children. Number three, these are children's hospitals with great credibility in billing these insurance companies. Number two, on the Medicaid side, 40% of patients in children's hospitals are Medicaid patients and these children are also being covered under a federal mandate that was put in place by the government in 1967, called EPSDT, Early Periodic Screening Diagnosis and Treatment, and that says if there's an FDA-indicated drug or device for children, Medicaid must cover it. If there are multiple options, Medicaid gets to choose. Fortunately for us, there is no other option. We're priced very fairly and we're getting coverage across the board on the Medicaid front. So, we now are currently finishing an additional six or seven studies, so we can get a Category 1 code in the next 18 months. We're also in the process - we've hired two of the country's most respected firms when it comes to getting written policy coverage - so, we're getting coverage now on a 64999 case-by-case basis, we're in the process of going and working on the written policy coverage, and then late next year, mid to late next year, we'll begin the Category 1 process. We've got strong support from the academic societies, which is necessary, the American Academy of Pediatrics and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. So, you have to have strong support from those academic societies in order to get the Category 1 code. From a margin standpoint, cost is about $74 to make this technology and it's roughly $1,200 is our sale price, we've got a 94.7% gross margin, each patient gets four devices over four weeks. So, if it was $4,800, it's almost $5,000 is the revenue per patient.

Ashley Matthysse (22:11):

Big-picture goals for the company. Can you touch on those?

Brian Carrico (22:19):

We're very close to profitability, as I said. We were very close to hitting it in July, we might hit it still in August, but regardless, in the next 30 to 60 days, we'll be fairly profitable, and the goals are pretty straightforward. We want to leave ourselves with three options. The board has decided that we want to be able to A, IPO, B, buy the investors out if they'd like to be bought out, and number three, we'd like the opportunity to exit and I think exit is the most interesting and most favored idea at this point. Like I said, we'd like to get our revenues to $30, $40, $50 million and exit on a 10 to 12 multiple in the next three to four years. That's really the goal.

Ashley Matthysse (24:16):

Michio, did you have something you wanted to add here?

Michio Painter (24:26):

So, the opioid crisis is a tailwind for us in one sense, because obviously it's brought a huge amount of awareness around the need for different therapeutics. There's also, you know, sort of much more scrutiny at the regulatory level because of the same concern, right? Everyone doesn't want to put out the next Oxycontin, so, we as a company sort of navigate these spaces and it might be interesting for everyone to hear just how your individual company and space is subject to those overall kind of conditions.

Brian Carrico (26:54):

From a headwinds standpoint, it's the reimbursement side. Although we're seeing 90% reimbursement, 88% reimbursement on commercial insurance, and we're seeing a 99% reimbursement side on the Medicaid side, you've still got children's hospitals that don't necessarily have the resources, the billing teams and the chief revenue officers to be in place to turn around and do the billing, they just don't have time for it. So, until you have a tracking code, or T code, or a bulletin, or some type of policy, they're a little reluctant to bring the technology in. So, I would call that a headwind. From a tailwind standpoint, we just continue to mount data. This is about data, it's about insurance and we continue, we're just now getting into great conversations, we're starting to work on policy with insurance carriers. This is just going to continue to mount, but the more data we get, the more our pipeline is incredible. Six or seven additional indications coming in the next 18 to 24 months, so it's just continuing to mount.

Michio Painter (28:23):

Yeah, that's great to hear. I mean, from my point of view both as an investor and as founder of a company myself, I think that we're really primed to see big wins in this space and I think that that's going to create a bit of a snowball effect. I'm way down on a pre-clinical aspect, but my company has benefited from about $5 million in non-dilutive funding from NIH and the DOD, so that's certainly been a huge help to me in the space.

Brian Carrico (29:44):

Sure, so first of all, I'll tell you from a debt standpoint, we've got about $300,000 in debt, which, you know, in the big picture is really not a big deal. From a non-dilutive funding standpoint I would tell you the biggest benefit to us is all of our research as a general rule, has been donated, and I say "donated", it's been done by grants through universities, we've just donated devices. So, we've had to pay very little, if anything, for research in the past several years and of the seven or eight studies that are ongoing, we only have one study that we're paying for, roughly $250,000 for a post-concussion study at Children's Hospital of Orange County. Outside of that, we're paying maybe $10,000 or $15,000 for a research coordinator, and we're donating devices. So, we don't necessarily have any non-dilutive funding, but when you're getting this type of first-class research at Duke, Cleveland Clinic, Ohio State, UCLA, Children's of Wisconsin, we've got two studies at UCLA now, another one at Children's Hospital of Orange County, these are first-class institutions getting these studies done for basically free has been incredible.

Michio Painter (30:47):

I've likewise had kind of tremendous support in the pain sphere, right? There's so many, it touches everyone, it touches everybody, right?

Steve Shapiro (32:07):

With COVID-19, where you're trying to do research and clinical trials, how has it been affected because all the resources from most of the research facilities are going to COVID?

Brian Carrico (32:24):

Well, on our side, we have not been affected. The children's hospitals are up and running, we're in really good shape, but we have not been affected. Fortunately, I will say a couple of the studies were delayed by a month, they were supposed to start in June, they didn't start until July, so that was the biggest delay, but we're moving forward now.

Brett Lanuti (32:45):

Yeah, and I think from our perspective, we've got eight sites currently that are part of a secondary study, it'll follow on the already-published data that we have and really, the headwinds there have been really just patient enrollment because those patients haven't been getting into the clinic, 'cause technically some of these back pain cases or patients are coming in and they're considered elective.

Ashley Matthysse (33:09):

Thank you for that question, Steve.

Brian Carrico (34:05):

Thank you all very much.

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