
**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

May 25, 2016

Date of Report (Date of earliest event reported)

INVIVO THERAPEUTICS HOLDINGS CORP.

(Exact Name of Registrant as Specified in Charter)

Nevada

(State or Other

Jurisdiction of Incorporation)

001-37350

(Commission File Number)

36-4528166

(IRS Employer

Identification No.)

One Kendall Square, Suite B14402

Cambridge, Massachusetts 02139

(Address of Principal Executive Offices) (Zip Code)

(617) 863-5500

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-
-

Forward-looking Statements

Statements in Exhibit 99.1 on this Current Report on Form 8-K may be “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “believe,” “anticipate,” “intend,” “estimate,” “will,” “may,” “should,” “expect,” “designed to,” “potentially,” and similar expressions as they relate to InVivo Therapeutics Holdings Corp. (the “Company”) or its management, identify forward looking statements, which include statements regarding the Company’s product development strategy, the Company’s clinical and operational milestones, the safety and effectiveness of the Neuro-Spinal Scaffold, progress toward achievement of the Objective Performance Criterion (OPC) for The INSPIRE Study, projections of cash reserves, the timing of the submission of the Humanitarian Device Exemption (HDE) and the likelihood of approval. Any forward-looking statements contained therein are based on current expectations, and are subject to a number of risks and uncertainties. Factors that could cause actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the Company’s ability to successfully open additional clinical sites for enrollment and to enroll additional patients; the timing of the Institutional Review Board process; the Company’s ability to achieve the OPC on a timely basis, or at all; the Company’s ability to obtain FDA approval; the Company’s ability to commercialize its products; the likelihood that current funds are sufficient to continue the Company’s operations through the end of 2017; and other risks associated with the Company’s business, research, product development, regulatory approval, marketing and distribution plans and strategies identified and described in more detail in the Company’s Annual Report on Form 10-K for the year ended December 31, 2015 and its other filings with the Securities and Exchange Commission, including the Company’s Form 10-Qs and current reports on Form 8-K. The Company does not undertake to update these forward-looking statements.

Item 7.01. Regulation FD Disclosure.

On May 25, 2016, Mark Perrin, the Chief Executive Officer and Chairman of the Board of Directors of InVivo Therapeutics Holdings Corp. (the “Company”) participated in an interview with BioNap, which was published on May 25, 2016. A full transcript of the interview is attached as Exhibit 99.1 to this Current Report on Form 8-K. The Company undertakes no obligation to update the information discussed in the interview in the future, except as may be required by law.

The information contained in this Item 7.01 and in Exhibit 99.1 referenced herein is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or incorporated by reference in any filing under the Securities Act of 1933, as amended or the Exchange Act, unless the Company expressly so incorporates such information by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Transcript of Interview with BioNap, dated May 25, 2016.
2	

SIGNATURES

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

INVIVO THERAPEUTICS HOLDINGS CORP.

Date: May 25, 2016

By: /s/ Tamara Joseph
Name: Tamara Joseph
Title: SVP, General Counsel & Chief Compliance Officer

3

Exhibit Index

Exhibit Number	Description
99.1	Transcript of Interview with BioNap, dated May 25, 2016.
4	

Transcript of Interview with BioNap, Inc., dated May 25, 2016

CEO Interview — Jason Napodano

Mark Perrin — CEO and Chairman, InVivo Therapeutics

JN: Let's start with a review of some recent news. Last month, you made a very important announcement that yet another patient has converted from AIS A to

AIS B. This patient was patient #6, who converted at two months after implantation. You now have four of the first six patients converting, and patient #7 is only one-month post-implant, so there's another potential conversion within that patient's six-month timeframe. Have you identified any trends with respect to injury type, injury location, time between injury, and surgery? Have you identified any predictive variables to conversion and, if so, do they suggest potential modifications to the INSPIRE protocol?

MP: No, we haven't identified any predictive variables. Conversions have occurred with high and low injuries and with surgeries that occurred within 24 hours after injury and for as long as almost four days after injury. Both the youngest patient in the trial, age 18, and the oldest patient in the trial, age 55, have converted.

JN: Even with the small number of patients, are there any preliminary assessments regarding the heterogeneity of the injuries?

MP: Yes. There are eight implantations and we are now classifying our patients into two categories: contusion, or closed injury; and compound, or open injury. We define a contusion or closed injury as an injury where the surface of the spinal cord is intact so that the surgeon needs to make a small incision to release the necrotic material from inside the cord. The *Neuro-Spinal Scaffold*TM (NSS) is then inserted into the resultant central cavity. A compound or open injury is an injury in which the surface of the cord has been traumatized so that it is no longer intact due to laceration or maceration by spinal bone fragments, shear forces, contusion or compression. When the cord is already open, the NSS is simply placed into the physical defect that the surgeon sees in the spinal cord. Of importance, we've had two patients with contusion injuries convert and two patients with compound injuries convert. We were especially impressed with the two compound injury conversions given the far greater degree of damage to the spinal cord.

JN: Did any of your preclinical work suggest this was possible?

MP: Actually, yes. The contusion injury models we studied in rodents and the pig were quite representative of the type of closed contusion injury we are seeing in patients. And the hemisection injury we studied in primates is anatomically similar to the spinal cord defects we see in patients with a compound or open injury.

JN: Unfortunately, you also announced that patient #8, who presented to the hospital with polytrauma, succumbed as a result of his underlying injuries. As this is a lingering concern for some of your investors, is there anything else you can tell us that was not in the press release? When will the Data Safety Monitoring Board (DSMB) and FDA review whether the NSS or the surgical implantation procedure were related, in any way, to this patient's death?

MP: First, I think everyone is aware of the HIPAA Privacy Rule. As such, there is very little more we can say about the eighth patient. As you know, the patient was severely injured, and sadly, he ultimately succumbed to complications from his underlying injuries. The update I can provide is that the DSMB for the INSPIRE trial has reviewed all the hospital data related to this patient and concurred with the principal investigator that the death was unrelated to the NSS and its implantation procedure. Subsequently, as with all severe adverse events, an SAE report was submitted to the FDA.

JN: That's helpful to hear. Let's return to the other patients and the conversions you're observing. How can you be sure the NSS is working and that it's not simply the reduction of pressure from opening up the spinal cord?

MP: As I mentioned earlier, two of the four conversions were in patients with a compound injury in which there was no pressure in the cord due to the laceration or maceration. In contusion injuries, the primary objective in releasing the necrotic material is to lavage the injury so the cavity is exposed for NSS implantation. The fact that the pressure is relieved is a secondary benefit.

JN: Then what is the primary mechanism of action of the NSS?

MP: Simply put, neural regeneration and remyelination. Whether the injury is a contusion or a compound injury, the NSS degrades and is replaced by remodeled tissue that is neuro-permissive, allowing neurons to regrow into or through the remodeled tissue. In both rodent and primate models, we have seen evidence of myelinated or insulated axons in this remodeled tissue in the region of injury. We believe that this same neural regeneration is occurring in our patients. This belief is supported by the fact that our first patient has experienced progressive improvement over the first year after injury and that one conversion happened six months after the surgical implantation — a time period beyond which the vast majority of improvement is expected to occur. Improvement over these long periods suggests evidence of neural regeneration, which would be expected to take place over many months.

In addition to neural regeneration, we have recently made the exciting preclinical observation that "remyelination of denuded axons" occurs three months after implantation of the NSS in rodents. The term "denuded axons" refers to the loss of insulation around spinal cord nerves, and "remyelination" refers to the reparative process whereby new insulating cells called Schwann Cells repair the site of demyelination. Demyelination is a well-recognized cause of neurological injury, and remyelination has long been a desired therapeutic goal.

JN: Do you think the conversions you're seeing are higher in your study because these patients are being hand selected and receiving care at some of the nation's top facilities?

MP: With regard to our clinical sites, we have a range of Level I trauma centers in the INSPIRE study. Of course, we select our sites to ensure we have both a surgical and rehabilitation team that can conduct a clinical study to the standards set forth by the FDA. The surgical procedure itself has been described by

our surgeons as very straightforward. Furthermore, there is no evidence that any particular rehabilitation protocol improves AIS conversion rates. With that said, there's no reason to believe the high conversion rates we've seen in our trial are due to the type of institution or rehabilitation protocol.

JN: Of the remaining 13 to be enrolled in the study, you need one more patient to convert to achieve the 25% objective performance criterion — or OPC — for INSPIRE. Is it that cut and dried?

MP: The FDA-approved protocol includes an OPC of 25% of patients converting from AIS A to another AIS category within the first six months following implantation. So yes, if we have one more patient converting from AIS A to another AIS category and all of the converted patients are considered evaluable, then we'll have indeed met the OPC for the study. The patients need to have 6 months of verified follow-up study data to be considered evaluable per the protocol.

JN: I understand INSPIRE is designed to enroll 20 patients, but does it make sense to approach the FDA if you have more than 50% conversions after the first 10 to 12 patients?

MP: If we meet or exceed the OPC before enrolling 20 patients, we'll likely approach the FDA to have a discussion about the potential for HDE approval. It really depends on the timing of events and the rate of enrollment. For example, if we have a high number of conversions in the first 10-12 subjects but enrollment picks up dramatically and we have many others in early follow-up, that may be a factor for the FDA. There is no guarantee that the FDA will allow for an earlier approval even if we've already met the OPC, and it's possible that the agency will require the full safety database of 20 patients before granting approval.

JN: Let's talk about enrollment, or the lack thereof. This seems to be the major issue investors are focused on. The trial is approaching two years and you've only enrolled eight patients. Can you give us a sense of why enrollment is so slow and what the company is doing to speed enrollment along?

MP: Let's start by looking at patient enrollment in the context of clinical sites joining the trial. Given the very innovative scaffold implantation procedure we were advocating, there was an understandable reticence in the neurosurgical community and it took one year after starting the trial to get just ten sites out of 217 Level 1 trauma centers to participate in our trial. In addition, there were FDA-mandated enrollment holds early in the study. With increasing enthusiasm by neurosurgeons, we now have 20 sites and enrollment has been picking up over the last several months.

Since February, we have had one patient enrollment per month. Even with this current run rate, we would expect to have 16 patients enrolled by the end of the year, but going forward we expect the average number of patients enrolled per month to increase over the course of the year. Since March, we've announced five new sites joining the INSPIRE study, and we have many more sites in the startup process, including sites in the UK and Canada. We are expanding to the UK and Canada in part because of their centralized referral patterns, where all patients with spinal cord injury are treated at one or two hospitals within a large geographic area. With all of these additional sites and new countries, our objective is to get average enrollment rates up to two patients per month and to approach full enrollment by the end of the year.

One more thing: I've been attending our principal investigator steering committee meetings for the past year and in my 35 years of pharma/biotech/device experience, I have never seen a group of key opinion leaders become so enthusiastic about a product in clinical development. This is clearly a reflection of the enormous unmet clinical need for SCI patients and the exciting clinical data we've generated to date. These leading neurosurgeons have shifted their thinking in a very big way. They are seeing the NSS as an important and entirely new approach that could significantly change how complete SCI is treated in the coming years, and they want to be part of this development process.

JN: Do you have a target date for full enrollment?

MP: Standing guidance is that we hope to approach full enrollment by the end of the year.

JN: How quickly after the last patient follow-up do you think you can file the application, and what's the standard review time for an HDE filing?

MP: We'll probably be able to file the HDE about two to three months after the last patient's six-month follow-up. The FDA has 75 days to review an HDE application, but the 75-day review clock can be stopped for questions or other reasons. On average, the FDA takes about four months to review an HDE application.

JN: By my calculations, there are roughly 2,000 thoracic patients per year that fit the INSPIRE entry criteria. That's a sizeable market given what I would suspect the device is going to cost, but clearly enrolling only eight patients over the past 18 months is making investors believe the commercial opportunity is small. How big do you see the market, in terms of patients, and why will commercial sales of the NSS ramp at a pace that far exceeds enrollment in INSPIRE?

MP: We are not yet making any revenue projections but we do envision a sizable market in the U.S. and globally. We're limited with an HDE approval to sell 4,000 devices annually in the U.S. Our HUD application was approved based on the number of all thoracic and cervical AIS A spinal cord injuries, excluding penetrating injuries. Upon approval of the NSS, we would work aggressively with the neurosurgical community, hospital administrators, and payers to ensure the NSS is available for as many patients as possible.

JN: Can you talk a little about what happens when the NSS gets approved?

MP: Our plan is to commercialize the product ourselves with a highly focused specialized and sophisticated sales team. Given our target audience, it's ideal for us to vertically integrate and to capture the entire gross margin.

JN: What's your goal for total study sites?

MP: We're now up to 20 sites in the U.S. We expect that we'll open at least six more sites in the U.S. as well as sites in Canada and the UK. We're actively recruiting new sites as we plan to roll many of the sites over into our cervical study.

JN: Let's talk about the company's plans for outside the U.S. Is there an HDE equivalent in the EU? What are the challenges or opportunities for starting a trial in Europe with the NSS?

MP: There isn't an HDE equivalent in the EU. Historically, the clinical bar for obtaining a European approval, a CE mark, has been substantially lower than obtaining a PMA approval in the U.S. However, the rules for obtaining a CE mark are changing and the path to approval is becoming similar to that for a PMA approval. In terms of running a clinical trial in Europe, we're already on our way to opening our first sites in the United Kingdom, which should happen in the next few months. In addition, we're currently evaluating whether to partner or commercialize ourselves in the major EU markets and Canada.

JN: What about the potential selling price for the NSS. It's early for this kind of discussion, but has the company engaged with payers or done any pharmacoeconomic studies you'd be willing to share with investors?

MP: We have begun to engage with payers and we're in the process of performing an extremely in-depth analysis on the pharmacoeconomic burden of spinal cord injury and the differences in burden between different degrees of injury. This will be an essential element for pricing discussions with payers and we hope to publish our findings within the next year.

JN: How do you think about pricing for a device like the NSS?

MP: We are not yet publicly discussing pricing and, of course, pricing will be in large degree determined by the INSPIRE outcomes data and our burden of illness analyses. At this time, we and analysts who cover us have used pricing in the range of \$60,000-\$150,000 per NSS.

JN: Remind us of the rules for profits under HUD. I believe you are allowed to sell as many devices as necessary to treat 4,000 patients. Clearly this is a large market, but are there restrictions that limit your ability to earn a meaningful profit under HUD?

MP: Profit is allowed if the device is intended and labeled for treatment of a pediatric subpopulation. The INSPIRE study permits enrollment of the pediatric subpopulation of patients between 16 to 21 years of age, and two of our patients already meet this criterion. Therefore, we expect pediatrics would be included in the NSS label and, as such, we would be able to make a profit on the NSS.

JN: What's the next trial for the company after INSPIRE has been completed and the application filed? Does it make sense to target AIS B patients with thoracic injury or perhaps AIS A patients with cervical injury?

MP: The next planned study, which we plan to initiate later this year, is a study of AIS A patients with cervical injuries. This patient population is included in our existing HUD designation. Following the cervical study, we hope to study AIS B and, potentially, AIS C patients. We are currently evaluating the best approval pathway for AIS B and AIS C patients, and will pursue the fastest and most efficient pathway possible. One potential regulatory strategy is to take advantage of the Expedited Access Pathway, or EAP, for a PMA.

JN: Do you think you could get better results by implanting the NSS into patients with AIS B or AIS C injury?

MP: It's difficult to speculate about results in patients with AIS B or AIS C injury at this time. However, patients with less severe injuries in general have less extensive damage to the cord, which may improve the likelihood or degree of tissue sparing, neural regeneration, or remyelination.

JN: Let's talk about your business development activities. The target population in the U.S. for acute spinal cord injuries is about 12,000 to 13,000 patients. This seems like a market InVivo can handle alone, but if a device company came along are you open to doing a deal for the NSS?

MP: I have always said "my ears have never gotten me into trouble." I would of course consider a potential acquisition offer, but our plan is to market the NSS by ourselves in the U.S and possibly the major markets in EU and Canada.

JN: Are you talking to anyone about U.S. rights or ex-U.S. rights to the NSS?

MP: We don't discuss any specific interactions but we have had and will continue to have discussions with several players in the space.

JN: Although you recently raised \$32 million, given the stock price, are you feeling any pressure to do a licensing deal?

MP: No. We feel we're in a position of strength given our balance sheet and the compelling clinical data we've generated, and that the right thing to do for the company and patients is to continue to build on the strong fundamentals we've established.

JN: When do you anticipate starting the first human trials with the NSS seeded with neural stem cells? Is there preclinical work that would need to be done prior to initiating a pilot study?

MP: At this time we don't plan on moving into the clinic with the NSS seeded with neural stem cells. Rather, our approach for treating chronic spinal cord injury is an injectable soft gel-like scaffold filled with neural stem cells that we refer to as our Bioengineered Neural Trails

program. This program is targeted at the enormous chronic SCI patient population and, along with the NSS, is aimed to achieve our mission to change the lives of all SCI patients.

JN: Are you talking with any stem cell companies right now?

MP: We have had and will continue to have discussions with neural stem cell companies. All of our work with neural stem cells is focused on the Bioengineered Neural Trails program, which combines neural stem cells with an injectable biomaterial delivered via a novel delivery device.

JN: How do you see that transaction playing out? What makes the most sense for InVivo to pursue? Clearly if you license cells from a public or private institution, they will benefit from sales of the seeded device as well, so does it have to be InVivo doing the licensing or, perhaps, acquiring?

MP: Let's just say that we're open to many types of transactions that continue to address the underserved SCI market while maximizing shareholder value.

JN: Would this pathway be as a drug or device?

MP: The Bioengineered Neural Trails program would be a combination product that would likely be regulated as a biologic by CBER, with assistance from the CDRH.

JN: What about the device you licensed from UC San Diego for your Trails program? What does the company plan to do with this technology? How does that fit in with the NSS?

MP: The device is a key component of the Bioengineered Neural Trails program. We are currently working with a well-known medical device product development company to design and build a clinical prototype of the device that we will test in both small and large animal models before talking to the FDA.

JN: Let's talk about the financing you just did. I speak to a lot of investors, and some were rather upset about the pricing of \$7.50 per share. I think the stock is worth a lot more than \$7.50 and it traded as high as \$10 just before the financing. That's hard to say when we sit below \$7.00 per share today, but it's still frustrating for investors to see a deal at \$7.50 when many believe the stock is worth multiples of that number.

MP: We're living in a time when the biotech and medtech markets are under tremendous pressure. Since July of last year, the NASDAQ Biotech Index is down over 30%. This puts pressure on institutional investors who have to deal with redemptions and protecting core positions, which makes raising money extremely challenging. Many mutual funds have not been participating in any financings for months. Numerous life science companies have tried and failed to raise money over the past eight months. It underscores that once again, cash is king and those companies with inadequate balance sheets will be facing some very serious challenges. We, however, were able to raise a significant amount of cash that we expect will allow us to complete the INSPIRE study. This means we don't expect future pressure on our valuation because of the overhang that occurs when a company needs to access the capital markets.

JN: Why the need for warrants?

MP: No CEO wants to include warrants in a financing. But as I just mentioned, the markets have been extraordinarily challenging and warrants have been a common feature in deals for similarly situated companies in 2016.

JN: You raised money earlier in the year through use of your At-The-Market facility with Cowen. You penned some thoughts about use of the ATM back in July 2015. Why the change in strategy to a public offering last month?

MP: There continues to be debate on the benefits and disadvantages of an ATM. I believe that an ATM can be an effective and efficient tool for raising capital in certain situations. And, I believe that a CEO should have as many tools in his or her toolbox for financing that strengthens the balance sheet while minimizing dilution. An ATM requires positive movement in the stock price, and unfortunately, we opened the ATM at almost exactly the same time as the medtech and biotech markets went into freefall. Given the continued weakness in the markets, a public offering was considerably more attractive for raising the funds that would be required to get us through HDE filing.

JN: Were there any notable investors that participated in the last financing? If so, was this the reason for the public offering?

MP: We continue to increase our level of institutional ownership, and after the most recent disclosures by institutions of their quarterly holdings our investors have noted that the Baker Brothers are now significant investors. I'm working to make additional long-term healthcare institutional investors part of our shareholder base.

JN: Please talk about the current cash position and use of cash over the next 18-24 months.

MP: We are planning for our existing cash to get us through the end of 2017 and by that time we expect to have filed an HDE for approval of the NSS. We also expect to be well along the way with our clinical investigation of the NSS in AIS A cervical spinal cord injury and significantly closer to the clinic with the Bioengineered Neural Trails program.

JN: Mark, your salary and bonus is a hot topic of conversation on the message boards. Can you clear up a little of the confusion I see out there about your current pay structure?

MP: Ah yes, my supposed \$2 million salary! My 2015 compensation structure is laid out in the proxy statement for all investors to see, but boils down to the following: my salary was approximately \$420,000; my bonus, based on performance, was \$215,000, other compensation was around \$200,000, and my stock options were a little over a million.

My 2015 salary represents a 3.5% raise over 2014. My bonus target is 50% of base salary and the Board's Compensation Committee deemed that we had achieved 100% of our 2015 corporate objectives. As far as other compensation, this comprises a housing allowance I receive and the

associated tax gross up. It is common practice for companies to provide a housing allowance until an employee's house is sold, so that the employee is not burdened by dual carrying costs. This addresses another frequently asked question of me. Yes, I am a full-time resident of Boston and have been since January 2014. I do indeed still own a house in Minnesota that has been on the market for several years and has been a real challenge to sell. To clarify a persistent rumor, I do not commute to and from Boston. Boston is my home. I think I'll show my Massachusetts driver's license and my Massachusetts voter registration card at this year's shareholders' meeting!

Back to compensation. A substantial portion of my cash and noncash compensation was in options, which aligns my financial interest with those of our shareholders. The SEC requires these awards to be valued using the Black-Scholes methodology. These options were granted at \$7.35 per share and they vest over a four-year period.

Finally, the compensation of the entire management team is benchmarked against our peer group company annually as determined by an outside consultant and thoroughly vetted and approved by both the Compensation Committee and the Board of Directors.

JN: How much stock do you personally own?

MP: I own 812,909 shares of options and common stock, representing 2.1% of fully diluted shares of the company.

JN: What percent is owned by current insiders?

MP: Officers and directors own 1,992,337 shares of options and common stock, representing 5.7% of fully diluted shares of the company.

JN: Another hot topic is the proposed increase in the number of authorized shares from 50 million to 100 million. Why the increase? Why now?

MP: This is really a housekeeping item. Whenever a company approaches the number of authorized shares, it's important to increase the number in order to maintain strategic flexibility. As of the most recent 10-Q, we have about 38.5 million fully diluted shares out of our 50 million authorized shares. Given the recent financing, I don't anticipate any need to raise funds in the near-term, but it's good practice to maintain a large number of authorized shares when there isn't a pressing need so nothing is signaled to the market. The extra authorized shares will give us flexibility for the next several years to pursue partnerships and/or acquisitions and to raise additional capital to support the launch of the NSS. I understand that the proxy advisory firm ISS, Institutional Shareholders Services, has recommended approval for this proposal.

JN: Where you do see InVivo in two years? Five years?

MP: In two years, I anticipate we'll be on the market with the NSS, which will be the first condition-modifying product ever approved for acute spinal cord injury. Given my commercial background, I'm really excited to launch this product into a space where so far there's been

nothing. Although we'll have challenges, I think we'll have the broad support and backing from the neurosurgical community to make the NSS the standard of care for treating acute spinal cord injury.

In five years, I think we'll be treating patients around the world with the NSS and will be seen as the leader in the field of spinal cord injury. In addition to the NSS, we'll have a deep pipeline of products dedicated to treating and improving the lives of all spinal cord injury patients.

Safe Harbor Statement

Any statements contained in this interview that do not describe historical facts may constitute forward-looking statements within the meaning of the federal securities laws. These statements can be identified by words such as "believe," "anticipate," "intend," "estimate," "plan," "will," "may," "should," "expect," "designed to," "potentially," and similar expressions, and include statements regarding the company's product development strategy, the company's clinical and operational milestones, the safety and effectiveness of the Neuro-Spinal Scaffold, progress toward achievement of OPC for The INSPIRE Study, projections of cash reserves, the timing of the submission of the Humanitarian Device Exemption (HDE) and the likelihood of approval. Any forward-looking statements contained herein are based on current expectations, and are subject to a number of risks and uncertainties. Factors that could cause actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the company's ability to successfully open additional clinical sites for enrollment and to enroll additional patients; the timing of the Institutional Review Board process; the company's ability to achieve the OPC on a timely basis, or at all; the company's ability to obtain FDA approval; The company's ability to commercialize its products; the likelihood that current funds are sufficient to continue the company's operations through the end of 2017; and other risks associated with the company's business, research, product development, regulatory approval, marketing and distribution plans and strategies identified and described in more detail in the company's Annual Report on Form 10-K for the year ended December 31, 2015, and its other filings with the SEC, including the company's Form 10-Qs and current reports on Form 8-K. The company does not undertake to update these forward-looking statements.
