Healthcare B2B Tech

WinSanTor

Ensuring no one suffers from Peripheral Neuropathy

WINSANTOR.COM SAN DIEGO CALIFORNIA

Peripheral neuropathy (PN) is one of the most significant unmet needs today, affecting 1 in 15 in the U.S. PN is the dying of nerves caused by many major diseases or injuries, e.g., diabetes, cancer/chemo, HIV, and genetic diseases. There is currently no treatment, only pain drugs that reduce all feeling. We are now in... more

Nigel Calcutt Co-Founder @ WinSanTor

Why you may want to support us...

1. CEO's prior two companies were acquired by Qualcomm and Apple, with technologies now standards in the industry.
2. Over $30M of non-dilutive funding (peer-reviewed grants rewarding innovation above 'hot' target trends) has driven the research and development.
3. Extensive evidence, including a proof-of-concept study in humans, showing a reversal of PN through 1) nerve regrowth, 2) reduced symptoms, and 3) return of quality-of-life to patients.
4. Having completed Phase 1 safety studies, we're entering Phase 2 early efficacy studies this year for our lead drug, WST-057, a study funded by the Canadian government.
5. The active ingredient in our drug is a historically safe drug used for 30+ years that is being 'recycled' to get to patients faster - increasing safety and lowering development cost and time.
6. Assemblage of nearly every stakeholder in diabetic peripheral neuropathy (DPN): clinicians, researchers, non-profits, governments, and, critically, patients.
7. To date, we have no outside investors. Our only true investors are our service providers, friends & family, and potential patients - all stakeholders who like where we are going.
8. The valuation of past companies attempting to treat DPN was several hundred million dollars after Phase 1 and several billion dollars after Phase 2.

Why investors ❤ us

WE'VE RAISED $2,125,588 SINCE OUR FOUNDING

Stanley Kim cares about people. He is particularly passionate about helping the many patients suffering from diabetic neuropathy and he wants to have the greatest impact possible to improve their lives. He is driven to help and I believe on a track to do just that. I'm cheering on his effort to alleviate the unnecessary suffering too many people are afflicted with.

Marc Hodosh

American entrepreneur, Co-creator of the TEDMED conference

I'm excited to be adding WinSanTour to my portfolio of investments and more importantly, supporting something that impacts friends of mine living with Diabetes. I look forward to seeing your future successes and being a part of the ride!

Scott Poniewaz

Founder & Fractional CMO at The Pony Group. TPG is a fractional CMO and business advisory services firm based in Austin, Texas. We help grow companies of all sizes across a variety of industries.

Hello, I am very excited about this venture! I believe the work that you are doing will help many people. I am a nurse and would love to help with anything you might need. I would especially be more than willing to assist in the clinical trials if a clinic opens at a location near me in Los Angeles, California.

Tess Faczan

I'm a mother of an incredible 7 year old girl whom I adopted at birth. I am a nurse by trade and I love what I do am very good at it.

SEE MORE

Our team

AND OUR MAJOR ACCOMPLISHMENTS

Nigel Calcutt

Co-Founder

Prof. of Pathology- UC San Diego, Lead Preclinical Contractor- NIH NIDDK-RAID, Expert in Neuropathy

Paul Fernyhough

Co-Founder

Professor in Pharmacology & Therapeutics at University of Manitoba, 20+ years in diabetic neuropathy

Lakshmi P. Kotra

Co-Founder

Director at Center for Molecular Design and Preformulations at UHN, Expertise in drug development

Stanley Kim

Founder

Angela Hansen

Vice President, Program Management and Regulatory

20+ years in drug development and clinical studies

Anne Lacey

Investor Relations and Patient Advocacy

Expertise in patient advocacy, donor relations, corporate sales, scientific research grant funding

Andrew Albertson

Controller

12+ years of corporate finance and accounting experience

In the news

Peripheral Neuropathy Affects 1 in 15 People

Imagine waking up every day and not knowing if you'll have the physical and mental energy to get up. Your body and limbs may be hit by numbness, burning, tingling (like when you hit your elbow), freezing, throbbing, cramping, or shooting pain. Now repeat this 24/7 and imagine it getting progressively worse, and that's what living with peripheral neuropathy is like. Over 30M Americans have this debilitating peripheral neuropathy (PN), including 60-70% of diabetics (DPN), 40% of cancer patients (CIPN), and 33% of HIV patients. There is nothing to treat the disease other than drugs that -- at best -- only suppress pain (e.g., opioids, gabapentin, etc.).

Life with PN can be miserable not only because there's no treatment, but because there is so little attention to correct the problem. For many, it is an invisible debilitation. At WinSanTor, we're here to fix that.

Our Discovery Regulates Nerve Growth

"Large pharma has now walked away from [diabetic peripheral neuropathy] as a result of [the] lack of basic understanding of the disease, while the enormity of the problem has reached epidemic proportions" (Berger et al., 2013)."

A decade ago, with no diabetic PN treatments on the horizon, leading government and non-profit stakeholders encouraged and funded two leading scientists in the field (Dr.

Paul Fernyhough, Univ. of Manitoba and Dr. Nigel Calcutt, University of California, San Diego) to find a cure. They discovered an entirely new mechanism regulating nerve growth. And more importantly, they discovered compounds which prevent and reverse nerve damage – specifically nerve damage caused by dysfunctional mitochondrial activity. This discovery is the origin of WinSanTor, and our continued success in advancing the science has warranted the winning of more than $30M in peer-reviewed grants.

We're Recycling an Already-Approved Drug

Patients with PN don't want to wait for help. They want and need an effective drug **today**. So we repurposed an existing drug (historically safe) originally approved over 30 years ago as a pill for stomach ulcers. We even made it safer by making it topical – rubbing on the skin a drug that millions have been taking orally for decades. This approach enables us to take safety "off the table" and focus on efficacy, which enables us to accelerate drug approval, decrease costs, and localize the drug where needed – on the peripheral nerves.

We Need a Drug that Works Today -- Not Tomorrow

Approximately 50% of all drugs sales by revenue are in the U.S., prompting most pharmaceutical companies to focus on maximizing profit in the U.S. But PN is a global problem that affects several hundred million people worldwide. So we're running international clinical trials to get drugs approved as expeditiously (time and money) as possible, because if performed properly, the results are transferable between countries.

We've shown:

- Proof of concept: This class of drugs is impactful in regrowing nerves, improving function, and giving patients their lives back.

- Our lead drug: The "best" of these drugs has successfully proved to be safe topically in a Phase 1 study in Australia.

- Indications: Our drugs appear to work not only for DPN, but in numerous animal models of other forms of PN.

In progress:

- Early efficacy trials: Phase 2 trials in Canada for DPN, funded by the Canadian government.

- Preparing for phase 2 dosing and efficacy studies in Europe, China and the U.S.

Planning:

- Pivotal multinational studies showing large-scale efficacy without adverse reactions beginning in Asia, then Europe and the U.S. We believe these studies will enable drug approval in the U.S. by 2021 for DPN and perhaps sooner elsewhere.

- CIPN studies for the 40% of all cancer patients affected – important and potentially faster to market.

Our Progress So Far

Normally, most companies will have raised over $50M to get to phase 2 trials. Most of our funding has come from committed stakeholders, not professional investors, and we're fortunate to have financial support from the public (gov't) and non-profit community - collectively, we've received over $30M in non-dilutive funding. Outside of grants, our only investments ($1.5M) have come from our service providers (who've seen our results), friends and family (who we want to do well) and potential patients (who have a bigger stake than financial gain). With the valuation of companies attempting to address DPN in the multi-billion dollars after phase 2, our success in trials will make our PN solution very lucrative.

In the end, patients are our priority, and getting our drugs to them is our primary goal. But beyond developing drugs that may reverse PN, we are committed to making sure the drug is affordable and cost-transparent.

So if we're able to hit our minimum raise of $300,000, we'll use the capital for drug manufacturing and planning trials. Funding above this amount up to the max of $1M will be used to initiate studies in the United States ($500,000), plan for studies in Europe ($100,000), automating review of biological samples ($50,000), and for Wefunder intermediary fees ($50,000).

Let's Cure Peripheral Neuropathy Together

To Wefunder Investors -

I receive an email nearly every day from at least one person afflicted with peripheral neuropathy. The stories are devastating. Peripheral neuropathy is not a disease associated with killing people, but it does. It is not a disease associated with telethons or movie stars, although it should be. At best, people only know about treating pain, which affects a fraction of the total PN population. Peripheral neuropathy is debilitating. It affects the daily quality-of-life of hundreds of millions of people, for the rest of their lives.

I'm not from the pharmaceutical industry, although I am from the scientific world. When Nigel and Paul asked me to start this company – based on their discovery of a means to reverse DPN by growing nerves back - I thought this would be a piece of cake (no pun intended). But then when I was told by industry people that there is no market for re-growing nerves, that we should develop new drugs to maximize profitability for investors, and that we should refocus on a quick exit; I wondered whether I had any business being in this business.

But I am a problem solver. My last two companies developed technologies that are now standards in their industry, something people use daily. Our drugs are too important for too many people for us not to overcome this challenge.

So we took a different approach. We are a lean startup (something from the technology world). We created a "normal" business strategy – figure out how to generate revenues soon and be good at it, and listen to our customers: doctors and patients. We took money from stakeholders who have a vested interest in the outcome, we repurposed a 30-year-old drug to get to market safer, faster and cheaper, and we are doing things a little differently. We are setting a new standard for the industry.

Our goal is to impact patients' lives today. If we do this right, we (and our stakeholders) will be rewarded very well. We will all do well by doing good. We started this by not being obligated to any investors, only patients. We are now comfortable initiating this campaign because we have at this point already made substantial progress toward an actual cure.

Look around. Ask around. Talk about it. 1 in every 15 people (1 in 8 adults over 40) has this disease (a huge market). Please join us in our fight to help patients, and hopefully share in our success as a stakeholder!

Stan Kim, CEO of WinSanTor

Look Around: Someone you Know has Peripheral Neuropathy

1 in 15	People suffer from peripheral neuropathy
1 in 8	People over 40 suffering from PN
over 30M	Americans who suffer from PN
$58B	Annual cost to treat diabetes-related chronic complications
50-70%	Diabetics with PN
40-60%	Cancer patients with chemo-induced PN
30%	HIV/AIDS patients suffering from PN
0	Number of approved drugs treating PN

Investor Q&A

– COLLAPSE ALL

What does your company do?

Peripheral neuropathy (PN) is one of the most significant unmet needs today, affecting 1 in 15 in the U.S. PN is the dying of nerves caused by many major diseases or injuries, e.g., diabetes, cancer/chemo, HIV, and genetic diseases. There is currently no treatment, only pain drugs that reduce all feeling. We are now in trials showing that we may be on track to reverse the disease, both biologically and functionally and, most importantly, to improve the quality-of-life for the millions affected.

Where will your company be in 5 years?

We are impatient. We are exploiting every strategy, mechanism, and regulation to accelerate approval of our drugs, including recycling a previously approved safe drug. Phase 1 is complete, and we are now starting phase 2. Our goal is to get drug approval in the U.S. by 2021 and perhaps sooner elsewhere. And by focusing on patient impact rather than the bottom line, we believe we're creating a new sustainable model for pharma companies based on patient need, not just money.

What is WinSanTor?

WinSanTor is a clinical-stage company focused on developing drugs to treat diabetic peripheral neuropathy.

Peripheral neuropathy is characterized as the degeneration of peripheral nerves and is caused by many different diseases. The most prevalent of these disorders is what's called diabetic peripheral neuropathy, which is caused by diabetes. At some point in their lives, 50% - 70% of all diabetics will have some form of degeneration of their nerves. It manifests traditionally as tingling, numbness, pain, and eventually, as it gets worse and worse, it can lead to ulcers and amputations. You know what it feels like when your leg falls asleep, or when you hit your elbow and get that tingling and the numbness? Imagine that 24/7. That's what peripheral neuropathy is like all the time. It can be painful. I get emails all the time from patients who are considering suicide. They look totally normal, but they are constantly in pain. There are a couple hundred million people with this disease, and currently, there is no treatment other than analgesics, like Lyrica or Neurontin, or painkillers, including opioids.

WinSanTor has two drugs in clinical trials that can reactivate mitochondria, the powerhouses of cells that tend to get switched off in people with diabetes. That switching off causes peripheral neuropathy; we can switch them back on.

We're currently testing on humans in different countries and we hope to get our first drug to patients in the next three years.

What is peripheral neuropathy?

Peripheral neuropathy is the degeneration or disease of the nerves. Peripheral describes the type of the neuropathy -- it means degeneration of the peripheral nerves, which are the nerves on the arms and legs, outside of the central nervous system.

There are many forms of neuropathy. Many people know Alzheimer's or Parkinson's. Those primarily affect the central nervous system. Peripheral neuropathy affects the nerves along the arms and the legs, which is why it manifests as tingling, numbness, and eventual pain in the arms and legs of patients.

What makes diabetics susceptible to peripheral neuropathy?

That's a good question. There are conflicting scientific explanations for why diabetics get neuropathy. We see that in most of the patients, up-and-down glucose levels can cause damage to the nerves themselves. What we find in many patients with diabetic peripheral neuropathy is -- and this is actually how the science works in our case -- is the mitochondria in the cells stop working properly.

Peripheral nerves are the largest users of ATP, or energy. Peripheral nerves require high levels of energy. In many patients with diabetes, the energy source for those nerves, the mitochondria, are dysfunctional. They're not working normally. They're just turned off for some reason, and we don't quite know why. But when the mitochondria themselves turn off, the first things that are going to suffer are the highest users of that energy, and those are the peripheral nerves. If you look at pictures of people with this type of neuropathy, you can see that these peripheral nerves, which are often stained in green, are just not there. Think of them like weeds that grow through the soil. Because they require so much energy, when the energy is no longer available, they slowly die off, to the point where they just regenerate further and further back. The first thing they lose is sensation, and then it eventually becomes other symptoms, like tingling and pain.

How many people have diabetic peripheral neuropathy?

The current statistics say this affects 50% to 70% of all diabetics. There are 415 million people in the world with diabetes. In the U.S., there are 31 million. Doctors say there are many more who are undiagnosed. The way many patients find out that they have diabetes, especially in third-world countries, is that they get this tingling, numbness, this sensation -- they get neuropathy, and then they find out they have diabetes.

Peripheral neuropathy can be caused by other diseases as well. About 50% of cancer drugs cause neuropathy. One form of HIV has been linked to neuropathy. According to the Foundation for Peripheral Neuropathy, 1 in 15 Americans has one form of neuropathy or another. If you walk around, especially with the older generation, you'd be amazed at how many people have neuropathy. That was actually one of the things that I discovered: This is one of the least talked about diseases out there. People that have the disease know about it, but other people just don't know about it. And sometimes people who have the disease don't realize what it is. It's underdiagnosed. One of the reasons for that is that there are not very many good diagnostic tests for the disease. The other reason probably is that it's not really widely recognized amongst the public. Everyone knows about cancer; everyone knows about Alzheimer's. But there hasn't been a strong campaign about neuropathy itself.

How did WinSanTor begin?

WinSanTor was created by leading scientific clinicians in the space of diabetic peripheral neuropathy. Currently, there is no treatment for peripheral neuropathy, so the leading stakeholders -- the National Institutes of Health, Juvenile Diabetes, and Canadian Health -- brought together the leading animal scientists, research scientists, and in vitro scientists to find a solution. That's how they found me.

They said, "We think we found something that can reverse the disease. Would you be interested in starting a company around this?" Kind of jokingly, they said, "We're not going to be able to pay you, because most of the funding is going to be through grants." Of course, I said yes. There are four founders: Myself, a scientist from Winnipeg, another scientist here in San Diego, and a third scientist in Toronto.

The name WinSanTor comes from the first three letters of the cities of the founders of the company: Winnipeg, San Diego, Toronto.

What do your drugs do?

We have discovered a new pathway that can reactivate mitochondria. Remember, mitochondria are the powerhouses of the cell, and they often get switched off in people with diabetes. We found a way to turn them back on. It's a brand new pathway no one had ever discovered. The target, the key that actually starts all this, is a known receptor, and we had developed a new drug for that receptor. But there are a number of compounds or a number of keys already out there that can turn that pathway back on. We're focused on two of them.

Because our purpose is to get a drug to patients as quickly as possible, we took an old drug that had been around for 30-plus years and was being used for stomach ulcers and repurposed and reformulated it. It was patentable, but it wasn't the extreme patent. It wasn't brand new, just new use, new formulations. We took that drug that had been around for 30 years, used by millions of people and is safe orally, and make it even safer by making it topical.

There's another drug that acts as another key, but it's not the most selective key. It hits on other things as well and causes other side effects. We took that drug and tested it on humans. We had extra money from NMAs and wanted to see if it actually worked. We tested it on about 50 patients, double-blinded, and that study should be published in the next six to eight months. That looks very promising. It actually shows that we reversed the disease in these patients. We know that we're on the right path toward developing a drug that could reverse the disease. When I say "reverse the disease," I mean that we saw nerves growing back, and we saw the functional deficits -- the tingling, the numbness, all those -- subside, and then we saw the quality of life return for the patients.

If these are old drugs, why haven't they been used for peripheral neuropathy before?

These drugs were originally used for other indications. The drug that was tested on humans -- the one that's non-selective and has not the best side-effect profile -- was used for overactive bladders, for people who would go to the bathroom too much in the middle of the night. It was never associated with mitochondria activity.

The other drug was used for stomach ulcers. It wasn't particularly effective 30 years ago and better drugs came onto the market, but it was shown to be very, very safe because it caused very few side effects over 30 years of use for that other indication. That drug was never approved here in the U.S., but it was approved in Europe and Asia. Our strategy there was, "Let's take this drug that has been approved in other countries and test it again in those countries to get it approved for our indication." It may allow us to get into those the markets faster, allowing us to leapfrog that drug for international use by taking advantage of where the drug was previously used.

This is a little different from most pharma companies. About 50% of all drug sales take place in the U.S., which means that we literally have as many drug sales in the U.S. as the rest of the world combined. If you're a small company, obviously you want to go where the money is. That means that you focus on the U.S. We opted to try and do this internationally and take advantage of this drug in those countries. That way, we can get it approved over there. The great thing about that strategy is that, for example, in China, there are 140 million people with diabetes. In fact, they claim that neuropathy is actually more severe there because patients may not know they have diabetes until they already have really bad neuropathy.

Why hasn't anyone solved this problem yet?

A couple companies have tried, but they've all failed. The reason these leading scientists were brought together was because there was very little momentum in this space, both historically and in the future. There've been a number of failures, and several companies have not done well. The other reason is, generally speaking, that neuropathy is a disease of the elderly and the poor. Diabetes is generally a disease of the poor. There aren't a lot of treatments for diseases like that.

Keep in mind that in the last several years, prices have gone up significantly for most drugs. The top 100 drugs have gone up probably about eight times in the industry, while the patient population has shrunk to about one-fifth of the original population they were treating. Everyone in pharma is moving toward what's called specialty treatments, where companies will develop treatments for patient populations of a couple thousand at most and seek to charge them hundreds of thousands of dollars. The days of large brand drugs, like Viagra, are gone. This is something that, as a tech guy getting into the pharma world, I didn't realize until I got here. I thought every pharma company wanted to make the next Viagra. Instead, everyone's going toward really, really, really small patient populations. I've heard of companies up to 20 people that are trying to treat 20 people. Everyone wants to treat the most expensive diseases, which are often end-stage cancer drugs. Meanwhile, there are millions of people living with diabetes and peripheral neuropathy, but very little commercial interest in those diseases.

Where are you in the drug development process?

Because we came from a different perspective -- the leading scientists, leading researchers, the leading clinicians, and the leading stakeholders -- our first priority, we decided as a group, was not to try and maximize profit. Our goal was to get a drug to patients as quickly as possible.

We are in clinical trials now. We're in Phase 1 in Australia and will start Phase 2 later this year. Most of our funding for this drug has come from government grants. We have raised very little money outside. We only started raising money in the last eight months, and most of that money came from patients and our service providers, who like the story so much that they want to be part of the story as well. Again, we approached this process not so much as, "Let's try and create a pharma company," but instead, "Let's try and see where this does and doesn't work, and see how far this goes." So far, it's working really, really well. In all clinical trials, you have to do three phases. Phase 1 is safety. Phase 2 is testing and early efficacy studies. You can do Phase 2 combined, or split it up into Phase 2A and Phase 2B, which means that you're just studying them even further in those areas. Phase 3 is efficacy studies. Once you get those Phase 3 studies approved, then you can get the drug approved in that country.

We're about a month away from finishing Phase 1 studies of our lead compound in Australia. That was basically taking an oral drug that had been used for stomach ulcers and applying it topically, on the skin, of healthy patients, to see if there's irritation or other side effects that were not seen orally. The second part, early efficacy studies, will probably start in Canada this summer. Phase 3 we'll have to do internationally. We're talking to a couple of Chinese companies right now. They'll pay for a good chunk of those studies in China for the Chinese market, but we can use that data back in the U.S. when we seek FDA approval. That's our goal.

How will you distribute WinSanTor's drugs?

Coming from outside this industry, I started realizing pharma is really good at marketing, paying for clinical trials, and distribution. But that's changing with companies like Aetna and CVS combining, or the Kaisers of the world, where they're starting to take a more active role in trying to reduce costs in the pharma world. For all intents and purposes, a pharma company is a middleman. They're good at distribution. Traditionally, biotech companies go through pharma companies to sell their drugs. But they're not the doctors and they're not the hospitals. They're the distribution networks. What you're starting to see now is Express Scripts and Cardinal Health going to hospitals and selling the drugs, which Pfizer dominated in the past. We'll see what happens in the future. I don't know what's going to happen, but I strongly believe that there will be fewer middlemen in the future than there is currently today.

How will you make money?

That's an interesting question because I don't think the pharma industry thinks like that. They think about how to get a drug to Phase 2 to sell the company. That's not us. The kind of investors that we want are those who are going to be stakeholders first, who want to make sure that we develop a drug. We may have to work with a big pharma company, and that's okay, as long as that company is in alignment with what our principles are: Developing an impactful drug for patients today, not maximizing profit on a drug that may or may not work.

What's your end game?

Most companies, by the time they finish Phase 3 trials, they're looking to sell the company. We're not. We're really trying to make as much impact as possible for patients. With most biotech companies, their customers are not the patients, not the doctors, not the insurance company. It's the executives in pharma that are looking to acquire companies. If you're developing a biotech company and you have to do research in this space to raise money, you need to go where the customers are. This is why there are so many companies that are doing cancer drugs, because there's so much money in cancer, and that's where all the investors are.

We're doing things differently. We're going to where the patients are, and if we do this right, our primary goal will be to treat the patients, ensure that we have a treatment that works for patients, makes patients' lives better. Let's say there are 50 million people who have neuropathy. If we capture 10% of the market at $1,000 apiece -- a price most drug companies would sniff at -- that's a $5 billion drug. We'd be one of the top 10 selling drugs ever.

Coming from the tech world, we don't look to sell a company first. We look to try and deliver a product to our patients, our customers. We're passionate about that, and so we've already started looking at other ways to get the drugs to patients faster. For example, it may be that we could get it to patients faster if we treat chemo-induced peripheral neuropathy, which affects about 50% of all chemo patients. If that's the case, then we can probably get the drug approved by 2020 and 2021 in the US. By that same time, we hopefully should have a drug approved in one of those other countries where the drug was previously approved, in Asia or Europe, in 2020 or 2021. We're trying to do as many things as possible to try and treat as many different patients as possible. We're already looking at second, third, and fourth-generation drugs. Long-term, we want to own this area, so there's no one else who can develop in this area.

Our goals are, first, to develop a drug that impacts today's patients. Second, if it works, we'll be developing a different model for pharma and biotech, and if we can take the same model and apply it to other areas, we would love to. We would love for people to come to us and say, "Look, we love what you guys did with your drug. Do you think you can help us develop our drug in this one specific area so that we can get to patients?"

What concerns do you have?

We have already been able to address one of the biggest concerns, which is long-term safety, by using existing drugs. It's been proven that our drug is one of the safest drugs out there. It's been in use for 30 years on millions of people. It doesn't have long-term side effects. That was one of those risks that was removed.

The second concern we had was that this pathway was completely novel. Would it work in humans? What we're seeing now is that it seems to be working on humans, so we're getting more and more confident. It seems to be working on humans. The next part, then, is whether we can get this further along, Phase 2 and Phase 3, and show those effects in a larger population.

From a business perspective, we're trying to de-risk this as much as possible. The Canadian government is paying for our Phase 2 trials, which is really nice. In Phase 3, hopefully we can actually get into areas where U.S. companies don't often go, like China. Most U.S. companies aren't in China for a reason. It's really difficult to get into that country, but if I can partner with a Chinese company that sells in China, knows China, knows the government and works with the government, and they pay for my studies, then that's another item that we de-risk.

The other remaining question is the distribution on our end. There is no treatment for neuropathy today, so one of the things that we did early on was that we talked to all the non-profits working in this space and developed partnerships. Working with those groups to try and create more awareness for neuropathy will help us at some future date, we think, for distribution, making sure that they make their customers and their patrons aware of what we're doing. That's another thing we've worked to de-risk.

IP is another area that's always a concern. I used to be an IP attorney. We had a really interesting experience in that our patent lawyers, our animal guys, our topical guys -- the guys that typically we'd be paying -- they actually gave me money, as investors, because they wanted to be part of the company. I had a conversation with our patent attorney, who's the managing partner of one of the larger IP firms. He asked me, "How should we proceed with this one patent question?" I said, "Mike, you're an owner now. How would you proceed? You own this technology as much as I do." I know that I'm getting the best IP advice because his patent is my patent.

Why are you raising money on Wefunder?

We've actually been approached by a number of patients who've been driven to the end while trying to find a therapy for peripheral neuropathy. There is no one that's going to hold my feet to the fire more than patients and other stakeholders like that. Although we could probably raise money from outsiders, having patients truly be our drivers forces us to make sure that we're delivering to patients, not to investors who are trying to maximize profits.

Why have you decided not to pursue capital from the pharmaceutical industry?

There was a study in the Journal of American Medicine in 2016 or 2017. They published a review of all the cancer drugs that were approved between 2002 and 2013 for solid tumor cancers. There were between 40 and 50 drugs approved during that period. The efficacy of cancer drugs is measured based on how much longer you live. Well, during that time period, the average price of cancer drugs had gone up several-fold. The average life extension for these drugs was 2.1 months. The more recent drugs are better -- there are drugs on the market today that have shown some really good efficacy -- but that wasn't always true. Between 2008 and 2012, 18 cancer drugs were approved, and 13 of those 18 had follow-up studies. They didn't show any extension of life at all, and only one showed improved quality of life, yet during that same time period, the average price of these drugs rose to more than $100,000. It's crazy. This is the industry that I live in now, and it's why I have such a hard time. It's the only industry where you can get away with raising prices 10% or 20% in a year because insurance covers it all. Pharma companies can increase prices and patients can never even know. It's absurd. So WinSanTor, as a group, has said, "Look, we're not going to play this game. We're going to make this drug as affordable as possible." We need to make money, sure, but if we charge what we think is reasonable, we'll still be billionaires because the market is so big. We'll make a ton of money, and so will all of our investors. That's possible without screwing the patients.

Why is your team uniquely suited to make this happen?

We've seen a lot of failures. The scientists I work with have seen a lot of failures, and the reason they wanted to design the company this way was because part of the reason they saw so many failures is that the science was being distracted for financial or reasons. The science didn't always win out. We took the approach of, "Let's try and kill this quickly, learn from all of our mistakes, and try and make sure it works right the next time."

The interesting thing is that if you were a true investor, only looking to make money in this industry, there are a number of companies that are developing nearly the same technology in the same area for the same patient population. You'll find several hundred companies developing the same technology with very slight modifications. One may seem safer, or they may have a slightly different binding affinity. If you're in the tech world, that's akin to writing a software in different source code for the same group. You would never do that. Maybe Python's a little bit better than Java, or maybe PHP's a little better than X, but at the end of the day, it's all about getting to the market first in a way that works.

We took a very lean approach. That's what makes us different. We have been simply reiterating amongst ourselves what works and what doesn't work, and then applying it to get closer to a drug that can treat patients. In the pharma world, typically, there is no lean approach. There's, "Let's just go and raise a ton of money, and make sure we don't get anything wrong and go in the same area, what everyone else is doing." Here in San Diego, a couple companies sold recently for several billion dollars. They were working on the same targets, the same patient population. Whether their drug works or doesn't work doesn't really matter, because they're already sold their company for several billion dollars, so they're paraded around town as the right answer. What kept me up at night in the past was that I felt like we were saying the same thing over and over again, and no one was really listening. That was the hardest part. Nowadays, we're making certain bets and taking certain risks. We believe that the industry itself is going to change, that pharma is no longer going to be Big Pharma as you currently see it, and you're going to start seeing more of the Amazon effect, where PBMs and hospitals and other organizations try to reduce costs and reach patients faster and more effectively. If that doesn't work, then our business model doesn't work. I think I'm right, but I'm not sure if I'm that good of a fortune-teller.

How did you choose your investment vehicle?

A SAFE gives the investor and the company a buffer for investments. The only companies that have claimed to regrow nerves are Sangamo and Viromed. Sangamo's drug failed and Viromed appears to be shifting their claims. Irrespective, the valuations after phase 1 were in the hundreds of millions and approximately several billion after phase 2 for these products. If the valuation of our company drops below the cap, the investor is protected by receiving a significant discount on their investment. If it pops above the cap, the investor is protected with an even greater discount (the cap). Phase 2 is a study of safety and early evidence of efficacy. We've attempted to de-risk our phase 2 – we've shown safety from the phase 1, and evidence of efficacy using a comparable drug affecting the same target.

Do you have an exit strategy for investors?

Our goal is to develop an impactful drug for patients. That said, we are looking for revenue generating partnerships, and entertaining vehicles that bring in new investors to come in and buy out existing shareholders (a strategy common in the technology field) including going public. We've offered to buy out our current investors and so far no one has had any desire to exit.

Financials

WinSanTor has financial statements ending December 31 2018. Our cash in hand is $2,000,000, as of September 2018. Over the three months prior, revenues averaged $99,626/month, cost of goods sold has averaged $0/month, and operational expenses have averaged $232,176/month.

At a Glance

January 1 to December 31

$1,181,568 [24%]
Revenue

-$2,124,767
Net Loss

$1,386,502
+529%
Short Term Debt

$175,000
Raised in 2018

$2,000,000
Cash on Hand
As of 09/20/18

INCOME BALANCE NARRATIVE

Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this offering. Some of the information contained in this discussion and analysis, including information regarding the strategy and plans for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Peripheral neuropathy (PN) is one of the most significant unmet needs today, affecting 1 in 15 in the U.S. PN is the dying of nerves caused by many major diseases or injuries, e.g., diabetes, cancer/chemo, HIV, and genetic diseases. There is currently no treatment, only pain drugs that reduce all feeling. We are now in trials showing that we may be on track to reverse the disease, both biologically and functionally and, most importantly, to improve the quality-of-life for the millions affected.

We are impatient. We are exploiting every strategy, mechanism, and regulation to accelerate approval of our drugs, including recycling a previously approved safe drug. Phase 1 is complete, and we are now starting phase 2. Our goal is to get drug approval in the U.S. by 2022 and perhaps sooner elsewhere. And by focusing on patient impact rather than the bottom line, we believe we're creating a new sustainable model for pharma companies based on patient need, not just money.

Milestones

WinSanTor, Inc. was incorporated in the State of Delaware in December 2011.

Since then, we have:

- CEO's prior two companies were acquired by Qualcomm and Apple, with technologies now standards in the industry.
- Over $25M of non-dilutive funding (peer-reviewed grants rewarding innovation and results) has driven the research and development.
- Extensive evidence, including a proof-of-concept study in humans, showing a reversal of PN through 1) nerve regrowth, 2) reduced symptoms including pain, and 3) return of quality-of-life to patients.
- We are now in the middle of Phase 2 early efficacy studies in several sites in Canada, with the first of these sites funded by the Canadian government.
- The active ingredient in our drug is a historically safe drug used for 30+ years that is being 'recycled' to get to patients faster - increasing safety and lowering development cost and time.
- Assemblage of nearly every stakeholder in diabetic peripheral neuropathy (DPN): clinicians, researchers, non-profits, governments, and, critically, patients.
- To date, we have no venture financing. We received several peer reviewed (results oriented) grants in 2019 that mitigated our reliance on venture funding. This was supplemented by WeFunder and a RegD investment.

Historical Results of Operations

Revenues & Gross Margin. For the period ended December 31, 2018, the Company had revenues of $1,181,568 compared to the year ended December 31, 2017, when the Company had revenues of $1,558,270. Our gross margin was 100.0% in fiscal year 2018, compared to 100.0% in 2017.
Assets. As of December 31, 2018, the Company had total assets of $35,500, including $31,888 in cash. As of December 31, 2017, the Company had $116,234 in total assets, including $109,627 in cash.
Net Loss. The Company has had net losses of $2,124,767 and net losses of $870,392 for the fiscal years ended December 31, 2018 and December 31, 2017, respectively.
Liabilities. The Company's liabilities totaled $1,711,502 for the fiscal year ended December 31, 2018 and $220,465 for the fiscal year ended December 31, 2017.

Liquidity & Capital Resources

As of December 31, 2018, the company has been financed with $1,738,747 in equity and $325,000 in convertibles.

We used the proceeds of this round as set forth in this Form C under "Use of Funds".

We are currently raising additional financing in excess of the proceeds received from

"Wefunder" financing in order to perform operations. Because of the complexities and uncertainties in establishing a new business strategy, it is not possible to adequately project whether proceeds from this future round will be sufficient to implement our strategy. This complexity and uncertainty will be increased if less than the maximum amount of securities offered in this offering is sold. The Company intends to raise additional capital in the future from investors. Although capital may be available for early-stage companies, there is no guarantee that the Company will receive any investments from investors.

Runway & Short/Mid Term Expenses

WinSanTor, Inc. cash in hand is $31,888, as of December 2018. Over the last three months, revenues have averaged $99,626/month, cost of goods sold has averaged $0/month, and operational expenses have averaged $232,176/month, for an average burn rate of $232,176 per month. Profitability will be dependent licensing our technology regionally or taking the drug to market. We intend to find a license partner by mid/late 2020.

The Company received a $2M grant (for 2 years) in late September (2018) that enables us to begin chemo-induced peripheral neuropathy studies. We also received a $3M grant (for 3 years) beginning in 2019.

We are now in several sites in Canada for our Phase 2. The Canadian studies funding has already been committed by the Canadian government. We are preparing for Phase 3 studies as we were informed by regulatory consultants that certain countries such as Japan and China may allow us to begin studies as soon as end of 2020. We are also in discussion with several companies, including in negotiations with companies in these countries, which includes licensing revenue. We are in discussion with the EB-5 program (Immigrant Investor Program) about providing a loan to the company.

A note from Wefunder. Unlike companies on the NASDAQ, early-stage startups have little operating history. Financial analysis is not as useful when there is limited data. It's more important to predict the size of the future market. If the founder achieves their vision, will enough customers pay the company enough money?

It's also common for fast-growing startups to lose money even faster: they are investing in future growth. In these cases, it's often better to check if the Cost of User Acquisition (CAC) is lower than the Lifetime Value (LTV) of that customer. If one spends $1000 today to make $10,000 over the next five years, that may be a smart bet. Amazon is a famous example of re-investing potential profits to maximize growth over 20 years.

Net Margin: -180%

Gross Margin: 100%

Return on Assets: -5,985%

Earnings per Share: -$0.13

Revenue per Employee: $236,314

Cash to Assets: 90%

Revenue to Receivables: ~

Debt Ratio: 4,821%

Winsantor Inc. Financial Statements 2018 2017 Reviewed.pdf

Winsantor Inc. Financial Statements 2016 2017 reveiwed.pdf

Risks

1 The Company may never receive a future equity financing or elect to convert the Securities upon such future financing. In addition, the Company may never undergo a liquidity event such as a sale of the Company or an IPO. If neither the conversion of the Securities nor a liquidity event occurs, the Purchasers could be left holding the Securities in perpetuity. The Securities have numerous transfer restrictions and will likely be highly illiquid, with no secondary market on which to sell them. The Securities are not equity interests, have no ownership rights, have no rights to the Company's assets or profits and have no voting rights or ability to direct the Company or its actions.

2 Our future success depends on the efforts of a small management team. The loss of services of the members of the management team may have an adverse effect

on the company. There can be no assurance that we will be successful in attracting and retaining other personnel we require to successfully grow our business.

3 *Our technologies are in an early stage of development and are unproven.* The effectiveness of our technologies is not well-known in, or accepted generally by, the clinical medical community. There can be no assurance that we will be able to successfully employ our technologies as therapeutic, diagnostic, or preventative solutions for any disease or condition. Our failure to establish the efficacy or safety of our technologies would have a material adverse effect on our business.

In addition, we have a limited operating history. Our operations to date have been primarily limited to organizing and staffing our Company, developing our technology, and undertaking pre-clinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our pharmaceutical product. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

4 *The results of pre-clinical trials and previous clinical trials for our products may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the FDA or other non-U.S. regulatory authorities.* Positive results from pre-clinical studies and early clinical trial experience should not be relied upon as evidence that later-stage or large-scale clinical trials will succeed. Likewise, there can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future study results. We may be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population of their intended uses. Success in early clinical trials does not mean that future clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other non-U.S. regulatory authorities despite having prior usage or having progressed through initial clinical trials.

Further, our drug candidates may not be approved or cleared even if they achieve their primary endpoints in phase 3 clinical trials or registration trials. The FDA or other non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from pre-clinical studies... more

5 *Some of our programs are partially supported by government grants, which may be reduced, withdrawn or delayed.* We have received and may continue to receive funds under research and economic development programs funded by state and federal governmental agencies. Funding by these governments may be significantly reduced or eliminated in the future for a number of reasons. For example, some programs are subject to a yearly appropriations process in Congress. In addition, we may not receive funds under existing or future grants because of budgeting constraints of the agency administering the program. A restriction on the government funding available to us would reduce the resources that we would be able to devote to existing and future research and development efforts. Such a reduction could delay the introduction of new products and hurt our competitive position.

6 *We rely on third parties to perform many essential services, and if such third parties fail to perform as expected or to comply with legal and regulatory requirements, our efforts to commercialize any products may be significantly impacted.* We rely on third-party service providers to perform a variety of functions related to the development of our products, key aspects of which are out of our direct control. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we have engaged third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information and related services. If the quality or accuracy of the data maintained or services performed by these third parties is insufficient, we could be subject to regulatory sanctions.

Details

The Board of Directors

DIRECTOR	OCCUPATION	JOINED
Lakshmi Kotra	Professor @ University of Toronto	2011
Stanley Kim	Executive @ WinSanTor	2011
Paul Fernyhough	Professor @ University of Manitoba	2011

Officers

OFFICER	TITLE	JOINED
Angela Hansen	VP Regulatory	2014
Stanley Kim	CEO	2011
Andrew Albertson	Treasurer	2017

Voting Power

HOLDER	SECURITIES HELD	VOTING POWER
Lakshmi Kotra	4,200,000 Common Stock	24.2%
Nigel Calcutt	4,200,000 Common Stock	24.2%
Paul Fernyhough	4,200,000 Common Stocks	24.2%

Past Equity Fundraises

DATE	AMOUNT	SECURITY
	$113	SAFE
05/2017	$1,377,939	Priced Round
07/2018	$175,000	Convertible Note

Convertible Notes Outstanding

ISSUED	AMOUNT	INTEREST	DISCOUNT	VALUATION CAP	MATURITY
07/31/2018	$175,000	6.0%	20.0%	$50,000,000	07/31/2020

Outstanding Debts

None.

Related Party Transactions

None.

Use of Funds

$300,000	95% for drug manufacturing, 5% for Wefunder fees
$1,070,000	35% towards drug manufacturing for clinical trials, 35% for toxicity trials to initiate studies in US, 25% for automating review of biological samples, 5% for Wefunder fees

Capital Structure

CLASS OF SECURITY	SECURITIES (OR AMOUNT) AUTHORIZED	SECURITIES (OR AMOUNT) OUTSTANDING	VOTING RIGHTS
Preferred Stock	1,425,000	1,013466	No
Common Stock	30,000,000	15,468,000	Yes

Form C Filing on EDGAR

The Securities and Exchange Commission hosts the **official Form C** on their EDGAR web site.