



Revolutionary New Small Molecule Drug for Preventing Contact Dermatitis caused by Poison Ivy, Oak or Sumac



Raymond J. Hage, Jr.
President and
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Hapten Sciences, Inc.

CEOCFO: *Mr. Hage, would you tell us the concept behind Hapten Sciences?*

Mr. Hage: We formed Hapten Sciences because we saw a gap. Many universities have tremendous research and technologies. They take them to a point. They really are not pharmaceutical development organizations; pharmaceutical development is very different from some of the early stage research that they do. Large pharmaceutical companies now have de-prioritized some of their research activities over the past few years and they might license or acquire the technology they want once the proof-of-concept is available. We saw an opportunity to step in the middle and acquire technology that is proven at a basic science level and then develop it to a point where it can either be fully developed and taken to market or it can be partnered with a company that may have significant late-stage research capabilities and a significant sales and marketing infrastructure.

CEOCFO: *It is a large arena; how do you assess what to take into the fold?*

Mr. Hage: Our lead product is called PDC-APB. The simplest way to think about it is that it is a synthetic component of urushiol, the irritating component in poison ivy, poison oak, poison sumac and other plants. We focused on that because there isn't anything available to prevent that (contact dermatitis caused by exposure to urushiol) today. We like the technology from the University of Mississippi and the inventor who is Mahmoud A. ElSohly. He is a great person, scientist and partner. They had the technology, good people and the technology is positioned to be a first-to-market drug. This is a condition where there isn't anything practical to prevent it and once you get contact dermatitis, there is not really much you can do except manage symptoms. You can take steroids and other things but it is really too late by then. When we licensed it, we thought and still do think it has a fairly predictable development path. We can easily find subjects that contract contact dermatitis due to poison ivy and measure the drug's effect. That is a good situation for us. We know the technology, we know the people to help develop it, it is on track to be first-to-market and it is a big market.

CEOCFO: *How did you come about the technology?*

Mr. Hage: The industry is very small and everybody knows everybody. The projects we have assessed including this one have been through word of mouth. People told me this might be something to look at. The co-founder of the company, Gary Prosterman is also well connected in the health sciences world. We have gone through the evaluation process for several drugs and tried to work with technology that makes sense for the market and our capabilities.

CEOCFO: *Where are you in the process with PDC-APB?*

Mr. Hage: The drug was awarded two STTR grants under NIH. That was before we licensed it. What we have done since we licensed it from the University of Mississippi is further characterization of the molecule - the active pharmaceutical ingredient (API). We have made the API under cGMP manufacturing conditions. We have performed additional preclinical studies both in safety and efficacy in appropriate models. We recently filed an investigational new drug application with the FDA and now we are preparing to begin clinical trials.

CEOCFO: *What is the science; how does it work?*

Mr. Hage: It is a small molecule that binds to protein and drives an immune response (Hapten). It is technically a drug but it works like an immunologic/vaccine.

CEO CFO: Will you be bringing it to market yourselves?

Mr. Hage: We are prepared and I think our investors are prepared to take this to market. That is one strategy and I think many people want to do that when they start a company. The other side is that you can partner with a pharmaceutical company that has a portfolio of products that already has sales representatives in place and a well established market presence. We are prepared to do either one. Partnering this with the right partner that will put a focus on it and has late-stage development capabilities and an established sales and marketing organization would be very attractive to us at the right time.

CEO CFO: What is the potential for this product?

Mr. Hage: Allergic contact dermatitis is the single most common plant allergy in North America. There are fifty million cases per year in America and more than seven million office visits. Fifty to 85% of people are susceptible to contact dermatitis in the US due to urushiol exposure. Most people if they have been sensitized to it, meaning they have seen it/been exposed previously, will have a reaction/rash to poison ivy. It is potentially a very large market. With that said, not everybody who gets poison ivy ends up running to the doctor because they will use some sort of calamine lotion or something or just wait it out. However, there is a significant percentage of people that have moderate to severe poison ivy rashes. There are occupational exposures – forestry workers, fire fighters, agricultural workers, line workers, etc. There are also many recreational exposures. Many people hunt, fish, garden, golf and are exposed. The ones that have a moderate to severe reaction end up going to the doctor and getting treated, often times with steroids.

CEO CFO: Do think as there is no remedy for this problem today, it would be easier to get the attention of the medical community?

Mr. Hage: This is brand new and we believe that if it is available people will want to have it. We have people email the company inquiring about if they can be in a clinical trial. Many avoid routine activities enjoyed because they do not want to get poison ivy. We believe that many around the country will welcome this. We think it is a lot more attractive, interesting and important than a ‘third or fourth to market product.’

“I think the most exciting thing about this is that it is a common well-known problem that causes people to change their lives and/or become very uncomfortable. There is nothing to prevent poison ivy, oak or sumac contact dermatitis today. Our data look promising. Our team is strong. This is potentially a very valuable, first-to-market product that can help many people. We are enthusiastic to continue development.” - Raymond J. Hage, Jr.

CEO CFO: Was that part of your criteria when you chose to work on this?

Mr. Hage: We had to have something that we could manage. Some fields are highly complex. We like this because the basic research that was done looked very good, it is a first to market product opportunity and we have a solid grasp of what it will take to develop it. It was quite by choice. We liked the fit with our criteria.

CEO CFO: Are you still looking at other projects or will you complete one before you take on something else?

Mr. Hage: We are always looking different therapies that might fit with Hapten Sciences and this particular drug related to poison ivy. Also, we are reviewing other opportunities that fit with our criteria and capabilities.

CEO CFO: You mentioned that Mahmoud A. Elsohly is a good man and a great partner. Is personality a factor in your choice?

Mr. Hage: It is very important. We worked with the University of Mississippi and licensed the product. People were very easy to work with, very welcoming, and wanted to work with us. That was important because this is a long-term relationship. The inventor, Mahmoud A. Elsohly, is a brilliant scientist who is very vested in this. You cannot throw technology over a wall and never look back. Mahmoud has had a chance to help us with the original studies that he did, and has remained involved all along the way. That collaboration or personality or what ever you want to call it is extremely important to us.

CEO CFO: Do you have the funding you need or are you looking for investment?

Mr. Hage: Like any early stage company in life sciences we are always open to increasing our capital base with new capital partners that are strategic.

CEO CFO: What are the worldwide possibilities?

Mr. Hage: Poison ivy, oak and sumac are North American issues. Also, poison ivy (urushiol) is a big issue in Japan. We have decided that we are going to initially focus on North America and probably out-license the product in Japan. We

have not had discussions yet but given where we are, we will probably try to have those soon. The other thing is there are people that travel internationally to the US and then go back to where they live much like how someone takes a vaccine when they go to Africa or other areas where they might need protection from a disease that doesn't exist in the USA.

CEOFO: *Why does Hapten Sciences stand out?*

Mr. Hage: We have assembled a very good team. My co-founder has a wealth of experience in life sciences and other areas. The team that is working with me is mostly virtual. We have been able to attract people that have reported to CEOs of various major companies that now work with us in key functional areas like regulatory, toxicology and manufacturing. They are having fun and love the project. We have very good support from the University of Mississippi and the inventor. I think the most exciting thing about this is that it is a common well-known problem that causes people to change their lives and/or become very uncomfortable. There is nothing to prevent poison ivy, oak or sumac contact dermatitis today. Our data look promising. Our team is strong. This is potentially a very valuable, first-to-market product that can help many people. We are enthusiastic to continue development.

Interview conducted by: Lynn Fosse, Senior Editor, CEOFO Magazine



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From Research To Reality

Hapten Sciences, Inc.

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