

Q&A with Dr. Sandeep Gupta, Founder, President and CEO of Asana BioSciences developing an Oral JAK/SYK Inhibitor for Moderate-to-Severe Atopic Dermatitis and Targeted Therapies for Advanced Metastatic Cancers



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“Asana is a unique company not only in how efficiently we are developing our drugs and executing our programs, but also in the depth and breadth of our portfolio. We are a highly efficient and experienced management team, which makes very good, timely, data driven decisions. Our efficiency is probably one of the best amongst our peers. We are developing a broad portfolio of assets in areas of high un-met medical need. We are working on fast follower targets, but at the same time, we are highly focused on differentiation from the competition and developing best-in-class drugs.” - Dr. Sandeep Gupta

CEOCFO: Dr. Gupta, what was the vision when Asana BioSciences was founded in 2014? What is the focus today?

Dr. Gupta, PhD: When we founded the company in 2014, our vision was to be a company that provides novel drugs, both small molecule and biologics, which address's unmet needs of patients and provide treatment options to physicians and payers alike. We are still involved in that endeavor. We have multiple programs in Phase II clinical development and a number of programs in Phase I clinical development. Our focus, as we started back in 2014, remains in the areas of inflammation/immunology and oncology. We are a drug discovery and development company and we have made significant progress towards our mission of delivering novel and differentiated treatments options to patients and physicians and addressing unmet clinical needs.

CEOCFO: What are you working on specifically? What are you trying to accomplish and what have you developed so far?

Dr. Gupta, PhD: We started as a drug discovery and preclinical development company back in 2014. As I indicated, we have progressed to become a clinical stage company. We recently demonstrated clinical proof of concept in moderate-to-severe atopic dermatitis patients (also known as chronic eczema) where we have shown that our drug ASN002, a novel inhibitor of JAK and SYK kinase pathways, provides very fast relief from chronic itch associated with eczema, as well as modifying the disease by reducing the inflammation towards normal, non-itchy skin; i.e. lesional skin to non-lesional skin. In addition, we have significant drug development efforts in the area of cancer, two of our molecules are currently in late Phase 1 clinical development using precision medicine approach.

CEO/COO: *What is happening in the body? What is it in your drug that is acting with the problem that makes a difference that has not been done before?*

Dr. Gupta, PhD: As I said before, we are developing our lead drug ASN002, an oral drug, for moderate-to-severe atopic dermatitis. Atopic dermatitis is driven by inflammation, when the body's immune system produces a number of immunogenic molecules, which are known as cytokines, and some other factors. When inflammation is manifested in the skin, it can lead to eczema or atopic dermatitis. There are other drugs which are in development or on the market, such as steroids and some antibodies, which do provide relief against itch and skin inflammation in atopic dermatitis. Our clinical proof of concept study showed that ASN002 provides very fast symptom relief, and also converts the diseased skin back to normal skin. It does so by targeting multiple cytokine pathways in the blood as well as directly in the skin, which has not been reported for other oral drugs. Therefore, we anticipate that in the current clinical trials, in which patients are treated for longer duration than in our proof of concept study, we will demonstrate a more durable response, resulting in longer term patient benefit and the opportunity to reverse the disease completely. In summary, our drug could potentially provide a disease modifying treatment that will make the skin of an atopic dermatitis patient return to normal, healthy skin.

CEO/COO: *What else is in the group that you are working on?*

Dr. Gupta, PhD: Another drug that we are working on in this arena of inflammation and immunology is a topical product. It is not a tablet or injectable, it is a gel that you apply to skin. We have shown that this drug, when applied on an animal that is scratching vigorously because of an itch, can provide fifteen plus hours of relief with a single application. This is unique because there are no other treatments that can provide such long-lasting relief with such a fast onset of action. We have compared the effects of our drug with other topical agents that only provide relief for an hour or two, so we are very excited about this differential characteristic and potential benefit to patients. This molecule, ASN008, will enter clinical trials in patients soon. We have finished all the safety studies and other activities needed for an FDA application to start the investigation of this new drug. Another major focus of the company's discovery and development efforts, outside of immunology and inflammation, is oncology. We are working on novel treatments for a number of cancers. Our approach in the cancer area is precision medicine. We are looking to develop drugs that target specific genetic mutations. In the body, when the cancer takes over, sometimes there are genes that get altered very specifically. A particular mutated gene can cause cancer cells to grow uncontrollably, at a much faster rate than normal healthy cells. What we are working on is to selectively target the products of these specific mutant genes to stop the tumor growth. We have two drugs in our clinical development pipeline right now that are being evaluated in humans in Phase I trials, and we are trying to move these programs into more advanced studies by early next year. Right now, we are looking at the dosing, safety and early clinical responses to understand how well the drug is working, and then we will study these drugs in patient populations with specific types of melanoma, non-small cell lung cancer, colorectal cancer and pancreatic cancer, etc. There is still a high unmet medical need for patients with these cancers as there are not many active and well tolerated treatment options available. We believe our drugs will provide new treatment options to these patients.

CEOCFO: *What have you learned as you have been working on these various drugs? What surprised you so far, if anything?*

Dr. Gupta, PhD: We have always known that drug development is not easy, there are many unknowns. The question is, when you are presented with certain bits and pieces of data, what do you do with it. One needs to make a decision whether to continue on the same path or if one should change course. What we have learned as a team, as a company, is to evaluate the data early and very critically as it is emerging from animal or patient trials, and then do course corrections as needed. Look at what would be the best path forward based on the data, come to a conclusion, and then move the program forward expeditiously.

CEOCFO: *Is there a place for gut feeling, given your experience that comes into play or is it strictly what you see in front of your eyes?*

Dr. Gupta, PhD: What is in front of your eyes is the data. Sometimes the direction you choose is not only driven by data alone, your past experiences also shape the future path. At Asana, ultimate drug development decisions are never based on gut feeling alone. There is a little bit of gut feeling involved for certain aspects, for example with how much risk you want to take in certain areas. It does come into the picture from time to time, but once again, we are a science and data driven company, so we don't rely much on gut feeling; we rely primarily on scientific and clinical data. When new data emerges, we critically review it and assess the options it provides us. As I said before, gut feeling is based on experience and is only used to choose between the viable options based on the data, rather than overruling data.

CEOCFO: *What has been the reaction from the medical and scientific community that is aware of what you are doing at Asana?*

Dr. Gupta, PhD: Clearly, there is a lot of excitement over what we are doing. It is important to understand that Asana BioSciences is a very small and young company, but we have been successful in parallel development of multiple drugs. The medical community and the opinion leaders look at our efforts in this area and they are quite pleasantly surprised with what we have achieved with a small, but experienced team and focused resources. We have been able to make decisions and move programs forward quickly from preclinical into clinical development. What they are also excited about is, again, our ability to look at the data and change course if needed. For example, we were initially developing our atopic dermatitis drug ASN002, a dual JAK and SYK inhibitor, for cancer. However, in the cancer trial we had also incorporated some measurements to keep an eye on what happens to the inflammatory process in general. When that data started to emerge and after evaluating those data, we had a choice to make. We had three options in front of us; whether to ignore inflammation biomarker data and continue our efforts in oncology where we were developing the drug in Non-Hodgkin's Lymphoma and certain other indications, and where we had seen good clinical activity; or start the development in immunological and inflammatory diseases in parallel. The third option was to stop oncology development and focus on immunologic disease such as atopic dermatitis and other immunologic diseases. The initial data was very, very interesting and intriguing, so what we ended up doing was creating a parallel effort first. Then we said, "Okay, we understand what happens in cancer patients, let us see what happens in atopic dermatitis patients." Therefore, we ran a quick, placebo-controlled study with high scientific rigor and tested the hypothesis. In a few months, we received the data

from atopic dermatitis patients and then evaluated our options. Now once again, we had three options. The drug was performing well in cancer. We were seeing certain responses; those data were quite interesting from the cancer's and from our patient's perspective. However, when we looked at the atopic dermatitis data, it was much more robust. At a small company, with the resources we had, now we had to decide whether to continue clinical development in two different therapeutic areas, or focus. We considered all available data, our understanding of the competitive landscapes in these areas, the potential for differentiation, and different paths to success. After evaluating all aspects, we decided to prioritize the development of the drug in atopic dermatitis and other immunologic diseases, with focus and full force.

CEOCFO: *Are you seeking funding, investments and partnerships as you move forward?*

Dr. Gupta, PhD: Yes, of course. As a young company, it is very important to continue moving on our path, generate the right data for our development products and take our programs to the decision points. But as you know, pharma/biotech is a large capital investment arena. Therefore, we always continue to evaluate interest in terms of partnering, strategic partners as well as investors. The question is - when do we think is the right time for us to tap external investors or strategic partners. Currently, Asana is a well-funded private company. Our investors are experienced, savvy and highly successful. They have pharma experience, as well as experience in other areas and are fully supportive of our efforts and plans. They are fully aligned with us on the long-term vision for the company and are committed to support our efforts in discovery and development. However, they are also aware of the fact that going forward, once we start registration-directed Phase III clinical development activities and commercialization of our lead asset, and in parallel advance our early portfolio of clinical pipeline candidates, the investment levels will be quite high. They are committed to supporting us but at the same time recognize that additional investors and partners may help maximize the opportunities. However, it has to be at the right time, at least from the value creation perspective, we need to be at the right spot in development of our products, at the right inflection point. We do not want to partner too soon or too late, so we believe that sometime in the middle of next year will be a good time for us to seriously consider and execute some of these strategic options.

CEOCFO: *When you are talking with members of the investment community is there a general understanding of what you are doing and how it might be different from others?*

Dr. Gupta, PhD: I think the investment community is very smart. They see a lot of things and they are aware of what is happening in the world of immunology or oncology and what kinds of drugs are being developed and what is hot. They clearly have their finger on the pulse, so they do understand what we are doing as a company. We have talked to a number of investors; there is a lot of interest, clearly, from the investment community. We continue to receive very good and positive feedback regarding our lead program ASN002, which we are developing in atopic dermatitis and also plan to evaluate in multiple immunologic/autoimmune indications. In addition, they appreciate that Asana has a broad development pipeline, which gives us multiple shots on goal, both in immunology and inflammation as well as in oncology.

CEOCFO: *Why pay attention to Asana BioSciences?*

Dr. Gupta, PhD: Asana is a unique company not only in how efficiently we are developing our drugs and executing our programs, but also in the depth and breadth of our portfolio. We are a highly efficient and experienced management team, which makes very good, timely, data driven decisions. Our efficiency is probably one of the best amongst our peers. We are developing a broad portfolio of assets in areas of high unmet medical need. We are working on fast follower targets, but at the same time, we are highly focused on differentiation from the competition and developing best-in-class drugs. We continue to execute multiple programs in parallel quite efficiently, and we have more INDs to be filed in the next three to six months. Therefore, we believe Asana can be viewed as an emerging pharmaceutical company, not as a single asset biotech. Indeed, there are multiple programs in clinical development. Our portfolio, efficient process of decision making, and execution of our programs is quite unique and attractive from an industry perspective.

