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Along with their Recent Approval for Biosimilar, RELEUKO™, Kashiv Biosciences has a diverse portfolio of Biosimilars, Bio-betters, m-RNA based, 505(b)(2) and NCEs

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"There is a great deal of diversification, and when you are with Kashiv you can learn different platform technologies. Kashiv BioScience as company has diversified platforms to learn, an innovative approach to apply and a fantastic culture to strive into. Therefore, yes there are so many opportunities."
Dr. Chandramauli Rawal

CEOCFO: ***Dr. Rawal, the first thing I see on the Kashiv Biosciences site is "Patient focused innovation.' What are you working on now, and why?***
Dr. Rawal: We are a biopharmaceutical company. We are currently working on a couple of diverse molecules, which are highly complex and with limited competition. In our portfolio, you see a mix of large molecules and small molecules. We have a very diverse portfolio in Kashiv Bioscience includes Biosimilars, Bio-betters, m-RNA based, 505(b)(2) and NCEs.

All medicines are high quality oriented, and focus is patient access along with treatment compliance. In Kashiv, we are not restricted to any therapeutic areas. Our main engine is R&D and innovation. When I say innovative, we also do some tweaking in the molecules, so we are trying to make them bio-better, in terms of patient compliance. That is why "innovative."

CEOCFO: ***What do you understand about biosimilars that perhaps others do not, that gives you an edge when you are developing something new?***
Dr. Rawal: Biosimilars are the molecules that are highly similar to the biologic molecules, in terms of physical characterization, biological performance and clinical efficacy. Analytical assessment is the most

important factor when you develop biosimilar molecule and need to have strong analytical capabilities from beginning.

CEOCFO: ***What are some of the challenges in creating biosimilars?***
Dr. Rawal: Biosimilar is not a generic molecule it is about proving similarity in terms of safety and efficacy. The biggest challenge I can see in biosimilars is getting interchangeability with biologic molecule, extrapolation to other indications, getting the consistency in manufacturing, achieving high analytical similarity, and different regulatory approval process in different countries. Therefore, proving the biosimilarity is the toughest, and getting the consistency in terms of manufacturing and development.
CEOCFO: ***What is in your pipeline today?***
Dr. Rawal: We have 6 biosimilar molecules, 3 505b2, 4 NCEs and 2 mRNA molecules (vaccine and therapeutics) in our pipeline. 505(b)(2) and NCEs are based on small molecules and focus is unmet needs, patient compliance and new drug delivery techniques.

CEOCFO: ***Kashiv recently received approval for the biosimilar, RELEUKO™. Would you tell us about that?***
Dr. Rawal: Releuko™ is our first biosimilar approval. We are currently manufacturing based in the US. We are the seventh company, worldwide, who got a USFDA biosimilar approval for this kind of a molecule, so this is a very proud moment for Kashiv BioScience.

CEOCFO: ***What will this particular biosimilar do? Who would be using it?***
Dr. Rawal: It is a support therapy for any oncology/chemotherapy drug. It will increase the white blood cells.

CEOCFO: ***Why has it been so difficult for companies to get approval for biosimilars?***
Dr. Rawal: First of all, developing biosimilars, as I have mentioned, is a very long process. It takes patience. There are many challenges in developing biosimilar molecules as discussed. We are looking at 5-6 years of development plus $50-60 Mn per molecule. Most important is regulatory guidelines, which is not properly layout for biosimilar approval. Some countries have more defined approval process than rest.

Therefore, not everyone has an appetite to spend and wait for many years to get it approved with so many uncertainties. That is why I think it is tough. We waited for 11 years for this approval, and we finally got it. It is long process, it is a patient game, and it takes commitment.

CEOCFO: ***What is the purpose of creating a biosimilar?***
Dr. Rawal: The purpose of creating a biosimilar is to reduce the cost of biologic molecules. Biologic drugs are very expensive, so the purpose of introducing a biosimilar is to reduce the healthcare costs. That is why we need more and more biosimilar approvals in the US, to reduce the healthcare costs. Patent accessibility and affordability is the only purpose.

CEOCFO: ***What are your next steps? How long will it take to get up and running? How do you introduce the biosimilar to the medical community?***
Dr. Rawal: We have a commercial partner through which we are going to launch the drug in the month of June. We are currently in the mode of manufacturing this drug at our Chicago facility, and by June we will be launching it into the market through payers and hospitals. We have a commercial partner who is going to do this with us.

CEOCFO: ***You mentioned the challenges in manufacturing. What do you need to overcome so that it is stable, and it is the same product all the time? Is it a matter of the equipment used? Is it a matter of the drug itself being stabilized? How do you get it to work the way it is supposed to all the time?***
Dr. Rawal: In terms of manufacturing and scalability, these are all live cells that we are growing and getting the protein out of. Every time that you grow a cell there will be some challenges for consistency. That is where you have to set your parameters in such a way. You have to set your manufacturing equipment in such a way that you get consistency all the time. Again, it is a matter of time. You have to scale up in the right way.

Another challenge is getting single use consumables on time, which are very, very expensive and get long lead items. Therefore, material management and manufacturing controls with right atomization are very important to be successful.

CEOCFO: ***Kashiv Biosciences has offices in New Jersey, Chicago, and India. Is it a remote team that works together? Are there different projects in different facilities? What is the structure?***
Dr. Rawal: Chicago is our microbial manufacturing site, where we got our first approval. There we make biosimilar products based on a microbial technique. Piscataway is our headquarters, and we are also manufacturing products based on monoclonal platforms, which are separate than microbial platforms. In India, we have a full-fledged centralize R&D center where we develop all of these molecules that I mentioned under development.

CEOCFO: ***Are you seeking funding or investment at this point in time?***
Dr. Rawal: No. It is a private company, and we are funded by private investors, so no at this stage.

CEOCFO: ***That is a good position for a drug development company. You do not hear that often!***
Dr. Rawal: Yes we are**.** The only thing we are looking for at this stage is to look for a CDMO opportunity for utilizing our Chicago manufacturing site. We are also looking for out licensing of a couple of our molecules, which we have developed up to Phase one.

CEOCFO: ***How do you actively reach out to achieve your goals?***
Dr. Rawal: We have a business development department where we can be reach out, or you can reach out directly to myself.

CEOCFO: ***What is the interest, overall, in what you are doing? Has there been less of an appetite to look at new drugs over the past couple of years? What do you see as the status of the marketplace and opportunity for you?***

Dr. Rawal: In the future, we are also trying to diversify ourselves into Bio-better biologics, gene therapy and cell therapies. Our current main focus is biosimilar, but soon we will move away from biosimilar and will be focusing more on those future therapeutic areas.

CEOCFO: ***There are many companies to look at in the medical arena. Why should Kashiv Biosciences stand out?***

Dr. Rawal: Because Kashiv BioScience is very diversified in development platforms, and various therapeutics areas like oncology, immunotherapy, infectious disease, rare disease etc. Plus, our development strategies are very innovative and focused in terms of cost, time and Intellectual property support.

We work on large molecules as well as small molecules. Only a few companies might be working on those. Plus, we have a different platform which can be utilized to develop various molecules like monoclonal antibodies, microbial, fusion proteins, and mRNA. Therefore, there are various platforms available with us. I think it is the very, very diversified portfolio-based company. Our focus is innovation and patient compliance, so that is why we stand out in the market.

CEOCFO: ***There is lots of opportunity for you!***

Dr. Rawal: There is a great deal of diversification, and when you are with Kashiv you can learn different platform technologies. Kashiv BioScience as company has diversified platforms to learn, an innovative approach to apply and a fantastic culture to strive into. Therefore, yes there are so many opportunities.