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New Proprietary Medicines for Metabolic and Rare Diseases Treatment

Dr. Harold E. Van Wart (Hal) - *CEO*

CymaBay Therapeutics (OTCBB:CYMA) is a clinical-stage biopharmaceutical company located in the San Francisco Bay Area focused on the development and commercialization of proprietary new medicines to treat metabolic and rare diseases with high unmet need. The company is committed to developing breakthrough medicines that improve the lives of patients and their families. CymaBay's clinical portfolio was seeded with the assets from an earlier metabolic disease company, Metabolex, in which more than $120M was invested to produce a robust pipeline.

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

CEOCFO: ***Dr. Van Wart, what is the concept at CymaBay Therapeutics?***
Dr. Van Wart: We are developing novel treatments for unmet medical needs in the metabolic disease area. Our lead drug product, arhalofenate, is a dual-acting treatment for gout that does both things the gout patient needs. It lowers uric acid in the blood and provides better control of their painful attacks called flares. Beyond that, we have a portfolio of other compounds that have the ability to address other unmet needs in the metabolic disease space.

CEOCFO: ***There are many unmet needs, how have you decided what to work on?***
Dr. Van Wart: In the case of arhalofenate, our lead product, we found through pre-clinical and clinical studies that the drug has the perfect attributes for addressing gout, addressing both uric acid lowering and flare suppression. Other drugs in our portfolio have the ability to be directed toward other unmet needs. What we try to do is to match the unmet need in certain indications with what we know our drug may be able to provide to the patient. For example, another drug in our pipeline called MBX-8025 had been in development for an indication called mixed dyslipidemia, which is a condition where the patients' LDL and triglycerides are too high and their HDL is too low. We carried out a clinical study showing that the drug corrected all those imbalances as well as did a number of other things that were very beneficial to the patient. We are now in the process of assessing whether we can direct these demonstrated attributes of MBX-8025 to other unmet medical needs that are higher in severity. We are looking at a series of orphan indications that could benefit from those actions.

CEOCFO: ***What do you understand fundamentally about metabolic disease and how to address the issues that others do not? Is there an approach you are able take building on what you have learned in the past?***
Dr. Van Wart: Our company has a rich history of doing fundamental science, primarily in the diabetes area, but we have now branched out to trying to understand gout and other metabolic diseases. In our previous life, when we were Metabolex, we had about 80 scientists working on understanding through genomic analysis of human tissue, which genes were up- and down-regulated and might be responsible for the dysfunction in various diseases. We still have that database of knowledge and we are trying to apply that as we go forward to repurpose our clinical portfolio for newer indications.

CEOCFO: ***What are some of the challenges you face as you do your research and in getting attention as well?***
Dr. Van Wart: We have shifted our focus now to emphasizing clinical development and have discontinued research. The challenges in clinical development are fairly generic. With clinical trials, you have to be mindful

to design them and execute them correctly. They are expensive and we are highly regulated, so we have all those generic problems that a drug development company would have. I think the secret to success is matching the ability that our drugs have to improve physiological processes (do what we call pharmacodynamics) in humans to match the unmet need in the disease.

CEOCFO: ***Are you funded to take all the steps you would like?***
Dr. Van Wart: We carried out a financing last fall in which we raised $38 million primarily to move our lead asset, arhalofenate, through its next value inflection point, which is a phase 2b study of 225 patients with gout. The goal of the study is to prove the differentiated product profile that we put forward. Like all biotechs, we are always going to be looking for opportunities to finance to raise the money we need to move the rest of our portfolio forward.

CEOCFO: ***Often, investors are somewhat cyclical or the investment community is somewhat cyclical in the healthcare area. Are metabolic diseases in favor these days?***
Dr. Van Wart: There are times when certain indications are on the upswing and others are falling out of favor. I think it is fair to say that one of the reasons we directed ourselves away from type-II diabetes is that investors perceive this to be a very difficult indication, particularly for a small company. On the other hand, there is a trend right now for investor to view favorably the development of drugs in so-called orphan disease areas. If not orphan disease, there are also opportunities in other high-unmet needs specialty indications where a small company might even be able to build its own sales force. I think those trends are there, we are mindful of them and we have factored that in to our strategy going forward.

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- Dr. Harold (Hal) E. Van Wart

CEOCFO: ***With gout, is it that there is not one medication that covers the cause and effect? What are you bringing to the table that is not available today?***
Dr. Van Wart: Gout is actually an under-appreciated and poorly treated disease. There are eight million people in the US who have a diagnosis of gout and approximately 3.3 million get some form of treatment mostly aimed at lowering uric acid levels, which is the underlying cause of the disease. Unfortunately, about one million of those patients continue to flare three or more times a year. It is the painful flare attacks that represent the biggest unmet medical need.

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CEOCFO: ***What is next? Lay out the next year or two for the company.***
Dr. Van Wart: In the next year or two, our primary goal is to make sure that we execute and conduct or phase 2b study for arhalofenate. At this point in time, that is our lead value driver. When that study is complete, the next step would be to go to an end of phase 2 meeting with the FDA and negotiate what the phase 3 program would look like. At that time, we will determine whether we want to do a license deal or strategic partnership with a larger company to help fund those trials. In the meantime, we are going to be looking for good ideas on how to repurpose some of our other drugs away from large primary care indications like diabetes into areas that might be more friendly for a smaller company and that we can do more capitally efficiently.

CEOCFO: ***What have you learned personally from previous ventures that is most helpful for you here at CymaBay?***
Dr. Van Wart: What we try to do at CymaBay is to develop drugs that have clearly differentiated product profiles. It is our belief that, in the modern era, getting reimbursement for new therapies is increasingly difficult and that it is essential to have a product profile that meets clearly defined medical needs in the patient and that is supported by very solid science and clinical data. The lesson we have learned is that it is very important to get every aspect of that process right to ensure success.

CEOCFO: ***Put it all together for our readers. There are many companies to look at in your category. Why does CymaBay excel?***
Dr. Van Wart: I think we have a highly differentiated lead product in arhalofenate that has the potential to improve the lives of gout patients. CymaBay has a very solid management team of ex-Pharma executives that are all happy to be carrying out drug development in a small entrepreneurial environment. We are highly focused on what we are doing. Our staff all have strong scientific backgrounds and are able to support the drug development with pre-clinical studies, when needed. All in all, I think that is a pretty good package.

BIO: Harold E. Van Wart, Ph.D. has served as CymaBay's Chief Executive Officer since 2003, a member of its board of directors since January 2003, and President since April 2001. He served as Chief Operating Officer from December 2002 to January 2003 and Senior Vice President, Research and Development from October 2000 to December 2002. From 1999 to 2000, Dr. Van Wart was vice president and therapy head for arthritis and fibrotic diseases at Roche Biosciences, a biopharmaceutical company. From 1992 to 1999, he was vice president and director of the institute of biochemistry and cell biology at Syntex Corporation, a biopharmaceutical company acquired by Roche Bioscience in 1994. From 1978 to 1992, Dr. Van Wart served on the faculty of Florida State University. Dr. Van Wart holds a Ph.D. from Cornell University and a B.A. from SUNY Binghamton. He currently serves on the Emerging Companies and Health Section Governing Boards of the Biotechnology Industry Organization (BIO), as well as on its board of directors. He also serves on the board of directors of BayBio.

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