Anthera Pharmaceuticals Inc
Form DEFA14A
April 05, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

SCHEDULE 14A
(RULE 14a-101)

INFORMATION REQUIRED IN
PROXY STATEMENT

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the Securities
Exchange Act of 1934

Filed by the Registrant þ
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Check the appropriate box:
o Preliminary Proxy Statement
o Confidential, for Use of the Commission Only (as permitted by 14a-6(e)(2))
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ANTHERA PHARMACEUTICALS, INC.
(Name of Registrant as Specified in its Charter)

(Name of Person(s) Filing Proxy Statement if other than the Registrant)

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"Of science and the human heart
There is no limit…
Just when you quit."
Bono

Dear Fellow Shareholders,

The pursuit of life-saving therapies has never been simple and continually presents immense challenges to our researchers, patients and stakeholders. In the nine years of Anthera's history it has always been the smallest things that have encouraged us to endure. Last month a simple call of thanks from a lupus patient, feeling better after having completed treatment in our open-label Blisibimod study, provided us with the emotional and human touch needed to refuel the engines. And though 2012 was a year of difficult outcomes, we made tremendous progress in our understanding of how Blisibimod may best help patients suffering from a variety of autoimmune disorders. At Anthera, never has our journey forward been clearer. Based on the results of our clinical studies, we enter 2013 leading a new approach for the treatment of autoimmune disease with Blisibimod in hopes of improving the lives of patients around the world.

Systemic Lupus Erythematosus – or lupus – is a chronic attack on human body tissues and organs from our own immune system. Lupus can cause life-altering conditions such as painful arthritis, skin rash, hair loss, oral ulcers and organ failure that limit a patient's ability to live an active and normal life. Sadly, research has only recently begun to make progress in treating lupus patients with only one novel therapy approved in the past 50 years. Throughout 2012 we released a variety of data from our PEARL-SC clinical study with Blisibimod – our lead product candidate. At the American College of Rheumatology in Washington, DC we presented results from the PEARL-SC study that indicate treatment with Blisibimod is more pronounced in patients who initially have more active disease and who are receiving steroids as part of their treatment regimen. Superior results were seen when using a greater threshold of disease improvement that required larger reductions in a patient's lupus disease scores. We have now set out to repeat those results in two pivotal clinical studies. CHABLIS-SC1 and CHABLIS-SC2, which will begin enrollment in 2013 and 2014 respectively, will include patients from over twenty different countries and two hundred clinical sites. Our objective with these two studies is to provide the best in class therapy for resolving the effects of lupus in patients who have been unable to achieve a response with the current standard of care.

Later in 2012, we presented additional data regarding the effects of Blisibimod at the Asian Lupus Summit in Manila. New data presented at this conference, specifically data outlining the potential benefit of Blisibimod on measurements of kidney disease, provided the clinical and scientific basis for a new program exploring the use of Blisibimod in patients suffering from Immunoglobulin A Nephropathy – or IgA Nephropathy. In IgA Nephropathy, a patient's own immune response is triggered by the production of abnormal immunoglobulins – proteins designed to attack foreign objects such as viruses or bacteria. Similar to other autoimmune diseases, these abnormal proteins become targets for our own immune system and form harmful microscopic complexes that deposit in the kidney. Over many years these deposits lead to kidney damage that limits the ability of the kidney to function and eventually patients deteriorate to a point where dialysis or organ transplant is necessary. IgA Nephropathy affects approximately 40,000 patients in the United States making it eligible for designation as an orphan drug product with the US Food and Drug Administration. In Asia, where the reported prevalence of IgA Nephropathy is higher, there may be millions of patients suffering from the disease who would benefit from a new therapy. Current therapies, such as high dose steroids administered over several months, attempt to resolve the symptoms of the disease, such as high blood pressure or leakage of protein into urine. But for patients with IgA Nephropathy, treatment with Blisibimod may represent the first opportunity to directly limit the biological pathway leading directly to the production of these abnormal immunoglobulins and, therefore, stop the insidious path towards kidney failure. Our proof of concept phase 2 study, BRIGHT-SC, will begin enrolling patients this year with plans to obtain preliminary measurements of kidney improvement later in 2013. Concurrent with BRIGHT-SC, we will meet with global regulatory agencies, including the US Food and Drug Administration and the Japanese Ministry of Health, Labor, and Welfare, to clarify the path to approval for Blisibimod in the US and Asia.

Our efforts to advance Blisibimod for patients with severe, autoimmune disease remain our top priority and the continual support of our shareholders in 2012 and 2013 has provided the foundation. Successful completion of two public offerings in the past 12 months has provided over $80 million in new cash for our clinical programs. Our commitment remains to utilize this capital in the most efficient and cost effective manner as we advance Blisibimod in two global clinical studies. We've elected to retain all global rights to Blisibimod as we accelerate through these next stages of development. As a result, other than small royalties and milestones to Amgen, we managed to keep substantially all of Blisibimod's potential future value.

In closing, all of us at Anthera remain proud and humbled by the support of our collaborators, doctors, nurses, patients, and investors who, in spite of the challenges faced by drug development, have placed their trust in our efforts to improve the lives of people with autoimmune diseases. We are determined to fundamentally shift and improve the future of these patients by providing revolutionary treatment options like Blisibimod. By doing that well, we will create extraordinary value for the patients we serve and for all of our Stakeholders.

Sincerely,

Paul F. Truex

Chief Executive Officer

April 2013