

# Changing Tomorrows



## Changing Tomorrows™

#### Dear Members of the Acorda Community:

AMPYRA<sup>TM</sup> (dalfampridine) Extended Release Tablets, 10 mg was approved on January 22, 2010 by the U.S. Food and Drug Administration (FDA) and is now available by prescription to people with multiple sclerosis (MS).

When I founded Acorda in 1995, it was with the purpose of someday taking discoveries from the lab and delivering them as novel medicines to people with neurological diseases. At the time, and many times over the past 15 years, it seemed that goal was a very distant star on the horizon.

Having now developed our first new medicine successfully, I can tell you that there are few human endeavors more complex, risky and demanding. That we have done so is a tribute to the enormous collective talent and perseverance of Acorda's associates. Great recognition is due also to our clinical investigators, study coordinators and clinical trial volunteers for their many contributions – without the participation of these individuals, medical progress would not be possible. In addition, our shareholders have been essential contributors to our success, in being willing to provide at risk the large amounts of capital necessary to pursue Acorda's work.

AMPYRA is the first orally administered drug approved for MS. It represents an important advance in the care of people with this affliction. As we continually hear from people with MS, walking impairment, particularly in walking speed, is one of the most devastating consequences of their disease. With the approval of AMPYRA, we are poised to make a real difference for many thousands of people with MS and their families.

Now that AMPYRA is approved, we are focusing on commercializing the drug in the U.S. The launch is being supported by our expanded sales team, which now includes approximately 100 in-field sales representatives. In addition, our teams of Regional Scientific Managers and Managed Markets professionals are educating physicians and payors about AMPYRA.

Several critical regulatory and business events in 2009 helped lay the groundwork for the launch of AMPYRA and the growth of Acorda. It was a very successful year, and I am pleased to briefly review some of the highlights. The early part of 2009 was consumed by preparation, submission, and subsequent re-submission of our New Drug Application (NDA) for AMPYRA. Our team did an outstanding job of responding to the FDA Refuse to File letter we received in March, and we re-filed in record time. Upon accepting the NDA, the FDA granted us Priority Review.

Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed, it is the only thing that ever has.

-Margaret Mead

Immediately following the acceptance of our NDA, we turned to preparing for the FDA Advisory Committee meeting on October 14, 2009. Following months of intensive preparation, our team presented a compelling case for the medical need for AMPYRA. One of the most moving experiences I've had during the development of AMPYRA came during the public comment session of the meeting, when people with MS and their caregivers spoke about the impact that their walking disability has had on their lives. At meeting's end, the Advisory Committee voted overwhelmingly that efficacy of AMPYRA to improve walking in MS had been demonstrated and that this was clinically meaningful for people with MS.

Last year we also conducted a rigorous selection process and announced a collaboration with Biogen Idec to market dalfampridine outside the U.S., where it is known as Fampridine prolonged-release tablets. Under the terms of our agreement, Biogen Idec has assumed responsibility for development and commercialization activities in all markets except the U.S. We are delighted to be working with them to make this therapy available to patients around the world. In January 2010, Biogen Idec announced regulatory filings in Europe and Canada; these filings are under review by the respective health authorities.

Our top priority in 2010 is the launch of AMPYRA. At the same time, we are tending to Acorda's future growth in three key areas: life cycle management for AMPYRA; advancement of our preclinical pipeline to clinical development stage; and acquisition of new clinical stage assets.

#### **AMPYRA Life Cycle Management**

Acorda's life cycle management team is exploring the potential for extending the exclusivity period for the AMPYRA franchise. AMPYRA has orphan drug status, which provides for seven years of exclusivity from the January 22, 2010 date of approval. In March 2010, we applied to extend two AMPYRA patents listed in the FDA Orange Book based on provisions in the Hatch-Waxman Act that allow for up to five additional years of patent protection based on the development timeline of a drug. These patents currently expire on December 6, 2011 and July 30, 2013. If both applications are granted, the Company will need to select one patent for extension.

In addition, we are prosecuting pending AMPYRA patents that were filed in late 2004 and early 2005, which, if issued, could provide additional patent protection.

Our team is also working on potential new formulations of AMPYRA and is exploring whether it would be valuable to study other clinical indications in neurology.

#### **Advancement of Preclinical Programs**

Our lead preclinical product, Glial Growth Factor 2 (GGF2), has been shown to be pharmacologically active in a number of cardiovascular and central nervous system conditions. In the first guarter of 2010, the Company filed an Investigational New Drug (IND) application for treatment of heart failure which was subsequently accepted by the FDA. We expect to initiate a Phase 1 single ascending dose clinical trial in heart failure patients in mid-2010. GGF2 acts directly on heart muscle cells, or cardiomyocytes. It is believed to improve the heart's ability to contract by promoting the repair of tissue damage resulting from heart disease or injury. Existing medications for heart failure primarily aim to modify the workload of the heart, rather than promote ventricular repair. If we are able to establish a proof of concept in human heart failure trials, we believe this will enhance the value of this asset and our ability to continue to examine potential neurological indications for GGF2 and related neuregulin growth factors.

Our remyelinating antibody program, led by rHlgM22, is moving through pre-IND toxicology studies and manufacturing scale-up. There currently is no therapy that repairs lost or damaged myelin in diseases such as MS, so that a successful remyelinating therapy would represent a novel advance in the treatment of such diseases.

We also are continuing to develop our chondroitinase product, which in preclinical models has shown the ability to enhance plasticity, and functional recovery, in the damaged brain or spinal cord.

The U.S. Food and Drug Administration approved AMPYRA on January 22, 2010. AMPYRA is indicated to improve walking in patients with MS. This was demonstrated by an improvement in walking speed.

AMPYRA was previously referred to as Fampridine-SR, and is an extended release tablet formulation of Dalfampridine (4-aminopyridine, 4-AP), which was previously called Fampridine.

Acorda's partner, Biogen Idec, filed regulatory applications in Europe and Canada for Fampridine prolonged-release tablets. There are more than 630,000 people living with MS in Europe, and approximately 50,000-75,000 in Canada.

#### **Asset Acquisition**

We are exploring the acquisition of clinical stage compounds in the neurology space. I believe that Acorda has demonstrated its ability to unlock both the scientific and commercial potential of neurological medications – first with the ZANAFLEX franchise, and more recently with AMPYRA. We intend to identify and look to acquire additional assets in neurology where we are enthusiastic about both the caliber of the science and the potential to address unmet medical needs.

The approval of AMPYRA was a transformational event for Acorda. With the achievement of this milestone, Acorda has taken a giant step toward realizing its potential to become a leading innovator in the development and commercialization of neurological therapies. On behalf of all my associates at Acorda, I extend my thanks to you, our shareholders, for your support of this important enterprise. I look forward to updating you on Acorda's continued progress.

Ron Cohen, M.D.

President and Chief Executive Officer

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