

*A path forward.*

ACORDA THERAPEUTICS, INC. 2010 ANNUAL REPORT

ACORDA<sup>®</sup>  
THERAPEUTICS





# Susan

Age 65

Primary-progressive MS

Diagnosed in 2000

**AMPYRA patient since 2010**



## Dear Members of the Acorda Community:

In last year's letter, I noted that the approval of AMPYRA<sup>®</sup> was a transformational event for our Company. As the year unfolded, it became clear just how transformational it was.

On March 1, 2010, our team implemented the commercial launch of AMPYRA<sup>®</sup> (dalfampridine) Extended Release Tablets, 10 mg following U.S. Food and Drug Administration (FDA) approval on January 22. AMPYRA addresses a critical unmet need for people with multiple sclerosis (MS): improving their walking. We therefore expected an enthusiastic response from both healthcare professionals and MS patients and their families. In fact, the response far exceeded our own projections, as well as those of Wall Street, making AMPYRA one of the most successful product launches in the MS space.

In the first 10 months of availability, approximately 40,000 people—roughly 10% of all MS patients in the United States—filled a prescription for AMPYRA. During that same period, more than 7,000 healthcare professionals wrote at least one prescription for AMPYRA and, based on this, we expanded our original call list of about 5,500 prescribers to approximately 10,000. Our commercial and medical affairs teams did an outstanding job of educating physicians and other healthcare professionals about the product's labeled indication, safety profile and managed care requirements, and also addressing logistical issues that arose due to the huge pent up demand for AMPYRA.

Studies have shown that approximately 65% of people with MS suffer from walking impairment at a given time; even with 10% of all U.S. MS patients having tried AMPYRA in 2010, a large unmet need remains to be addressed. We have now established a strong base of consumers and healthcare providers who have positive views of the AMPYRA and Acorda brands. In 2011, we plan to build on that success by presenting new data analyses and expanding our education to prescribers about the broad range of appropriate patients who could potentially benefit from

AMPYRA. We are also launching new live and online programs to increase consumer awareness of AMPYRA and encourage appropriate patients to discuss initiating therapy with their physician.

We experienced some growing pains in our first year on the market. The pent up demand for AMPYRA among early-adopting physicians and patients was substantially larger than we anticipated. While that contributed to a very successful launch, the volume of prescriptions initially outstripped our ability to process requests, resulting in delays in filling and shipping prescriptions. We met this challenge, and also took it as an opportunity to improve the overall customer experience for healthcare professionals and patients in filling AMPYRA prescriptions. I was pleased with the rapid and innovative responses of

our commercial team—from adding more resources at our customer support center to identifying new ways to expedite processing and shipping prescriptions. By early September, we were able to resolve the prescription backlog generated by the pent up demand, and the process improvements we implemented have contributed to high customer satisfaction with our support services. There were also expected challenges related to reimbursement, and we were pleased with AMPYRA's overall reimbursement status at year end. Thanks to an excellent job by our managed markets team in educating healthcare plans about the benefits of AMPYRA for their subscribers with MS, approximately 75% of covered lives had minimal to no restrictions, and several of the largest plans in the U.S. put AMPYRA on Tier 2 formulary status. About 25% of covered lives had restrictive prior authorizations. Our team continues to meet with managed care organizations to provide further education and additional data from the marketplace.

**Approximately 40,000 people with MS tried AMPYRA in 2010, which represents about 10% of MS patients in the United States.**



In January 2011, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a negative opinion to our partner, Biogen Idec, recommending against the approval of FAMPYRA (the proposed trade name for AMPYRA® in Europe). We were disappointed by this decision and are working closely with Biogen Idec on a formal appeal. We are also working with Biogen Idec to respond to a Notice of Deficiency that was issued by Health Canada.

**Approximately 7,000 healthcare professionals wrote at least one AMPYRA prescription in 2010.**

The success of the AMPYRA launch in the U.S. resulted in \$133 million in net AMPYRA sales for the 10 months of commercial availability in 2010, approximately double the consensus Wall Street projections at the time of launch. Together with net Zanaflex Capsules® and Zanaflex® sales of \$48.5 million, this resulted in Acorda's first quarterly profit in the third quarter. Year-end cash, cash equivalents and short-term investments were approximately \$240 million, a result of appropriate management of our resources, even in a launch year requiring significant investments.

While the launch of AMPYRA® was the most significant event for Acorda in 2010, several additional accomplishments deserve to be highlighted as well.

The Zanaflex franchise again provided a meaningful financial contribution to our Company, with \$48.5 million in net sales for the year. We have brought patent infringement litigation against a generic manufacturer who has filed an abbreviated New Drug Application (ANDA) to enter the market prior to expiration of our patent in 2021.

We made significant progress on developing our pipeline, including the initiation of a Phase 1 clinical trial of Glial Growth Factor 2 (GGF2) for patients with heart failure in

December 2010. This milestone was especially noteworthy because GGF2 is the first compound that Acorda has successfully shepherded through the preclinical process and into human trials. In animal studies, GGF2 has shown the ability to improve the heart's function to relieve heart failure. These effects are believed to be related to GGF2's ability to promote the repair of heart muscle tissue damage resulting from heart disease or injury. Existing medications for heart failure primarily aim to modify the workload of the heart, rather than to promote repair of the injured tissue itself; GGF2 therefore represents a novel approach to treatment. We also published data showing that GGF2 can restore function in animal models of stroke, even when the treatment is administered up to seven days after the actual event. An accompanying editorial noted that this long treatment window is unique in the stroke literature and potentially represents an exciting opportunity for clinical development.

rHlgM22, our remyelinating antibody being developed in partnership with the Mayo Clinic, completed the majority of required preclinical studies, including cGMP (Good Manufacturing Process) manufacturing testing and pilot toxicology studies. Our R&D team is currently working on GLP (Good Laboratory Practice) toxicology studies. If the GLP toxicology results are acceptable, we plan to file an Investigational New Drug (IND) application with the FDA to begin clinical trials studying the ability of rHlgM22 to stimulate remyelination in people with MS. Currently there is no therapy that repairs myelin in people with MS. rHlgM22 represents a novel approach, and potentially a significant advance, in the treatment of this terrible disease.

My belief in the intrinsic value of Acorda remains firm; however, as a fellow shareholder, I have shared your disappointment that our stock price did not always reflect our performance over the course of 2010, particularly with regard to the highly successful launch of AMPYRA. Nevertheless, as we move into 2011, I see significant opportunities for Acorda to create value for shareholders. Acorda's Board of Directors and management team have identified three priorities that we believe position us to do so:

1. Maximizing the AMPYRA opportunity
2. Advancing our existing pipeline into the clinic
3. Pursuing accretive product acquisition opportunities

Our top priority is to maximize the AMPYRA opportunity. First, this means that we must drive demand in the United States, so that as many appropriate patients as possible have the opportunity to try AMPYRA. Our commercial team is rolling out new campaigns directed toward healthcare professionals and consumers. One feature of this campaign is a focus on AMPYRA data that showed clinically meaningful improvements in walking across the entire spectrum of walking impairment that was studied, from the least to the most impaired, indicating that even patients who are relatively early in their disease course may benefit from AMPYRA. At the same time, our scientific team continues to develop and present new data analyses from our clinical trials that highlight the unique benefits that people may experience when taking AMPYRA regardless of their clinical sub-type of MS.

We are also pursuing all available avenues to extend the exclusivity period for AMPYRA®. As this report goes to press, I am pleased to report that the United States Patent Office, or USPTO, has notified us that they have allowed the claims of our 2004 patent application, which pertains to the use of AMPYRA to improve walking in people with MS – our labeled indication. The term of this patent extends into 2026. This is in addition to AMPYRA's orphan drug status, which provides seven years of exclusivity from the January 22, 2010 approval date. We have also applied for patent extension under the Hatch Waxman Act, which allows for up to five additional years of protection based on the development timeline of a drug. The two patents under consideration for potential Hatch Waxman extension currently expire on December 6, 2011 and July 30, 2013, respectively, and have both been found by the USPTO to be eligible. In the next stage of this process, the FDA must determine by how much time, if any, these patents may be extended.

We are working on other potential life cycle extension strategies, including the development of new formulations of dalfampridine and exploring additional indications for AMPYRA in MS and other neurological diseases.

Our second priority in building shareholder value is to advance our existing pipeline. If we are able to establish proof of concept for GGF2 in human heart failure trials, we believe this could significantly enhance the value of this asset and our ability to examine both potential cardiac and neurological indications for GGF2 and related neuregulin growth factors. Similarly, if we are able to advance our remyelinating antibody to the clinic and achieve proof of concept as a reparative intervention in MS, we should add significant value to this product.

**In December 2010, Acorda initiated the first Phase 1 trial of GGF2 in patients with heart failure. GGF2 represents a unique approach to treating heart failure by repairing cardiac muscle and improving the heart's ability to pump blood.**

Our third priority for growth is business development. We are seeking to leverage the key assets of the company in these endeavors. From my perspective these assets are, first, a team that has been highly successful in identifying non-obvious neurology opportunities and developing them creatively through clinical and regulatory challenges. To leverage this asset, we are seeking product opportunities that we view as having high therapeutic potential and that are undervalued relative to

their commercial prospects, if approved. Ideally, these compounds would have safety data in humans and possibly proof of concept or additional efficacy data as well. Our second major asset is a commercial organization that has years of experience in marketing and selling successfully to neurologists. To leverage this asset we are exploring products that could be commercial as of

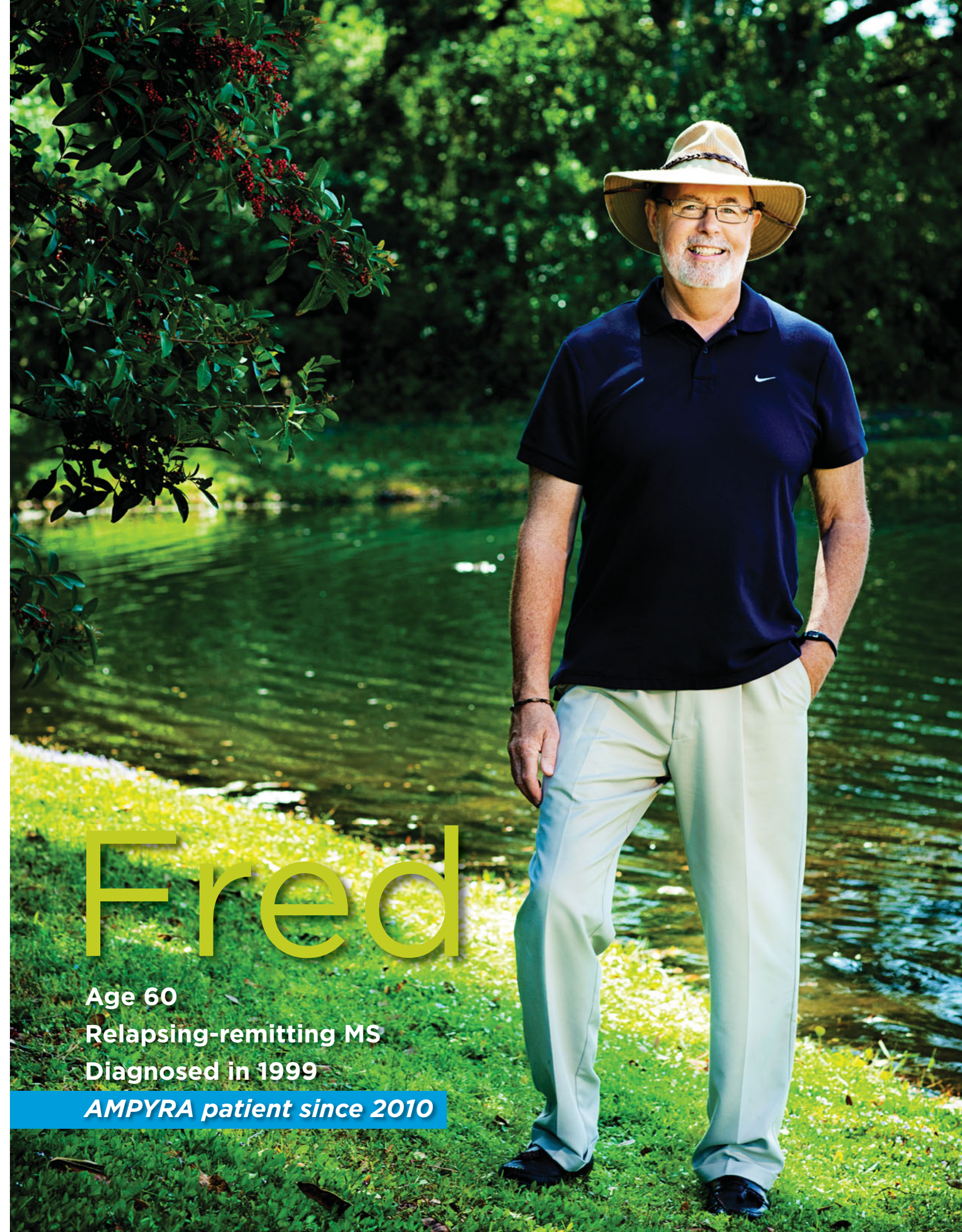
next year or beyond, and which may benefit from Acorda's co-promotion or outright acquisition.

At the beginning of 2010, we announced a corporate goal to in-license at least one compound in the neurology space by the end of the year. We explored several potential opportunities, but ultimately did not bring in any products because we did not find an asset that met our criteria on terms that we found reasonable. I believe that our thoughtful approach to this process and decision not to in-license assets in 2010 should provide investors with confidence that Acorda's management team is exercising prudence and seeking an appropriate balance between cash flow generation and investment in our future growth.

In 2010, we achieved a transforming milestone for Acorda, fulfilling the Company's mission to deliver an important therapy to people with a devastating neurological disorder. AMPYRA provides Acorda with the opportunity to build significant shareholder value, as well as to develop additional therapies that may improve patients' lives. Thanks to you, our shareholders, for your ongoing support as we work to build the leading biotechnology company in the neurology space.



**Ron Cohen, M.D.**  
*President and Chief Executive Officer*



**Fred**

**Age 60**

**Relapsing-remitting MS**

**Diagnosed in 1999**

**AMPYRA patient since 2010**

## Management Team

Ron Cohen, M.D.

*President and Chief Executive Officer*

Andrew R. Blight, Ph.D.

*Chief Scientific Officer*

Jennifer Burstein, M.B.A., CPA

*Vice President, Finance*

Anthony O. Caggiano, M.D., Ph.D.

*Vice President, Research & Development*

Kerry Clem

*Vice President, Sales*

Denise Duca, Ed.M.

*Sr. Vice President, Human Resources*

Herbert R. Henney III, Pharm.D.

*Vice President, Medical Affairs*

Douglas Kargman, M.D., M.S.

*Vice President, Drug Safety*

Ruhi Khan, M.B.A.

*Vice President, Business Development*

David Lawrence, M.B.A.

*Chief Financial Officer*

Adrian L. Rabinowicz, M.D., FAAN

*Sr. Vice President, Medical Affairs*

Kent Rogers, M.B.A.

*Vice President, Managed Markets*

Lauren Sabella

*Executive Vice President, Commercial Development*

Tierney Saccavino

*Sr. Vice President, Corporate Communications*

Brian Walter, Ph.D.

*Vice President, Regulatory Affairs*

Jane Wasman, J.D.

*Executive Vice President,*

*General Counsel and Corporate Secretary*

Thomas C. Wessell, M.D., Ph.D.

*Chief Medical Officer*

## Board of Directors

Ron Cohen, M.D.

Sandra Panem, Ph.D.

Barry Greene

Lorin J. Randall

Peder Jensen, M.D.

Steven M. Rauscher

John P. Kelley

Ian F. Smith



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