

Every step
is a story.



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Dear Members of the Acorda Community:

In 2008, we launched the *I Walk Because* campaign at National Multiple Sclerosis Society Walk MS events across the country. Our flagship outreach initiative to the MS community, *I Walk Because* provides an opportunity for the many people living with MS and their families to make their voices heard, allowing them to tell the world why they walk and about the people with MS they care about. Their stories have inspired us as we work to develop novel treatments for MS, spinal cord injury and related neurological diseases. I am pleased to report that Acorda Therapeutics took several important steps toward that goal in 2008.

As this letter was going to press in the second quarter of 2009, the FDA accepted for filing our New Drug Application, or NDA, for Fampridine-SR, assigning it Priority Review and a Prescription Drug User Fee Act (PDUFA) date of October 22, 2009. The PDUFA date is the target date for the FDA to complete its review of the Fampridine-SR NDA. Acorda submitted the Fampridine-SR NDA to the FDA on January 30, 2009, and subsequently received a Refuse to File (RTF) letter from the FDA. The letter cited the need to correct "format issues" and requested additional supporting information before the NDA could be accepted for review.

Data from the first Fampridine-SR Phase 3 trial in MS, MS-F203, were published in the February 28, 2009 edition of *The Lancet*. The publication was an important validation from the medical community of the interest in and need for new treatments that can improve neurological function, particular walking ability, for people with MS.

Acorda announced results from the second successful Fampridine-SR Phase 3 trial in MS on June 2, 2008. A significantly greater proportion of people taking Fampridine-SR in the trial had a consistent improvement in walking speed compared to people taking placebo (42.9% vs. 9.3%), as measured by the Timed 25-Foot Walk ($p < 0.0001$).

Acorda employees staffed the *I Walk Because* booth at 10 MS Walk events across the country in 2008. More than 60% of the 35,000 attendees at those walks participated in the *I Walk Because* program, either by posting a video to the *I Walk Because* web site, designing a personalized t-shirt with a message about why they walk for MS, or responding to a questionnaire.

To learn more about the *I Walk Because* program, visit www.IWalkBecause.org

I was pleased that our regulatory team was able to address the FDA's comments about three weeks after receipt of the RTF letter, and that the FDA accepted the NDA for filing less than two weeks later. The FDA's assignment of Priority Review status gives us a PDUFA date that is about a month and a half earlier than we expected at the time of our original NDA filing on January 30.

This was our first NDA filing as a company, and I want to recognize the extraordinary efforts of the Acorda associates who contributed to completing the application, which included data from more than 55 clinical studies dating back to the early 1990s and more than 700,000 pages of documentation. I also would like to extend my appreciation to the Fampridine-SR trial investigators, coordinators and study participants for their contributions to the Fampridine-SR clinical program. The commitment of MS centers throughout the U.S. and Canada and the willingness of people with MS to volunteer for studies of potential new therapies has been essential to the success of the Fampridine-SR program to date.

This program encompassed years of preclinical and clinical research; in 2008 alone, we successfully completed two clinical trials: a thorough QT (tQT) cardiac study and our second Phase 3 trial, MS-F204, demonstrating improved walking ability in people with MS. In the tQT study, at both therapeutic and supratherapeutic doses, Fampridine-SR was found to be no different than placebo with regard to the potential to cause an increase in the electrocardiographic QT interval. The FDA requires tQT studies for all new drugs seeking regulatory approval, as increases in the QT interval (corrected for changes in heart rate, or QTc) may signify an increased risk of developing malignant cardiac arrhythmias.

"We were there so that the voice of those who suffer from MS could be heard. As an employee, I am very proud to be affiliated with a company that truly cares about the community we serve!" —Nellie Catania, Legal Department Administrative Assistant

The results of our MS-F204 trial confirmed the results of our first Phase 3 trial, MS-F203, which we had unblinded in September 2006; a significantly greater proportion of people taking Fampridine-SR in the MS-F204 trial had a consistent improvement in walking speed compared to people taking placebo (42.9% vs. 9.3%), as measured by the Timed 25-Foot Walk ($p < 0.0001$). Additional measures of clinical meaningfulness, strength and spasticity in this study were also positive and consistent with the results of MS-F203. Importantly, an increased response rate on the Timed 25-Foot Walk was seen across all four types of MS, and regardless of background therapy.

We were also pleased that the results of MS-F203 were published in the prestigious medical journal *The Lancet* in February 2009.

Along with the clinical and regulatory progress of Fampridine-SR, Acorda achieved notable milestones in 2008 that are critical to driving long-term shareholder value: advancement of our preclinical pipeline; expansion of our commercial operations in preparation for the potential launch of Fampridine-SR; continued development of a commercialization strategy for Fampridine-SR in Europe and rest of world; and management of our financial position to successfully maintain operations and Fampridine-SR pre-launch and launch initiatives.

In 2008, we continued to advance our preclinical programs toward human clinical trials. Our work with the neuregulin family of proteins has led us to focus efforts on preparing our lead candidate, GGF2, for an Investigational New Drug, or IND, application in congestive heart failure. Acorda's expertise and history are in developing neurological therapies, but we believe that the scientific evidence for exploring GGF2 in the treatment of congestive heart failure is compelling. We anticipate filing an IND to support human clinical trials in late 2009, pending the successful completion of toxicology and other preclinical activities. We believe that if we are able to establish a proof of concept and can then enter into a partnership with a

cardiovascular-focused company, this would more efficiently move GGF2 forward in a cardiac indication, while potentially providing Acorda the capital to support our work on GGF2 in neurological indications.

Our remyelinating antibody program, led by rHIgM22, also continued pre-IND toxicology and manufacturing scale-up activities in 2008. Unfortunately, our external manufacturing partner was affected by the economic downturn and filed for chapter 11 bankruptcy reorganization. While this caused a delay in the program, we have subsequently identified sites to complete manufacturing and purification of rHIgM22. We expect an IND to be filed once we complete toxicology studies and have manufacturing capabilities in place to support the clinical program.

From a commercial perspective, our sales and marketing team continued to demonstrate their deep understanding of the neurology marketplace and excellence in meeting the needs of customers. Based on their efforts, sales of Zanaflex Capsules and Zanaflex tablets showed continued growth in 2008, and the franchise was cash flow positive on an operating basis for the first time since we launched in 2005. The Zanaflex franchise also remains an important strategic asset, supporting full commercial operations that provide Acorda with the experience and infrastructure needed for a successful U.S. launch of Fampridine-SR, if approved. In addition to supporting the Zanaflex franchise, this group has developed a comprehensive consumer and physician disease state awareness program in the U.S., focused on how walking disability affects people with MS and improving patient-physician dialogue on this topic.

We are exploring potential partnering opportunities for commercialization of Fampridine-SR in Europe and other markets outside the U.S. As we determine our commercialization path in

"I am excited to be able to work for a company that 'walks the talk.' We keep the patients first in our thoughts every day. Being at those walks I was able to see that the Acorda way is truly different." —Erica Breskin, Zanaflex Sales Operations

these markets, we are preparing for a centralized MAA filing in the EU and a NDS filing to Health Canada.

Notwithstanding the difficult economic climate in 2008, Acorda was able to complete two successful equity offerings following events that generated significant shareholder value – the results of our tQT study and the MS-F204 Phase 3 trial. The Company raised net proceeds of over \$200 million in those two financings and finished the year with \$246 million in cash and cash equivalents. Based on our current projections, this will enable operations through the end of 2010. Our balance sheet affords us the opportunity to make business decisions based on building the Company's value, rather than operating reactively in response to short-term variables. In particular, I believe our cash reserves have put us in a position of strength as we explore commercialization options in Europe and rest of world, and will allow us to properly fund the launch of Fampridine-SR in the U.S, if approved.

In this regard, we expanded our scope of operations in 2008, hiring approximately 40 new employees in areas such as managed markets, regulatory, marketing, and others critical to the successful launch of a product with the potential of Fampridine-SR. As we focus on growing our company and advancing our products, we continue to recognize that Acorda and our shareholders will benefit to the extent that we successfully develop and bring to market medicines that can have a meaningful impact on the lives of people affected by neurological disorders. Our commitment to patients and their families remains the cornerstone of our efforts.

As I noted at the start of this letter, we launched *I Walk Because* in conjunction with the National MS Society's Walk MS program. Based on the outstanding response to this program in 2008, we expanded *I Walk Because* in 2009 by becoming the national sponsor of Walk MS, with a presence at 14 of the largest Walk MS events in the country. In the course of attending *I Walk Because* events last year, we heard

repeatedly that the journey of each person with MS is highly individual, like the disease itself, with each family having different expectations, goals and definitions of success. To reflect the many ways that MS affects individuals and families, we have established “Every Step Is a Story” as the theme of our 2009 *I Walk Because* program.

I attended several *I Walk Because* events in 2008 and 2009, as did all of Acorda’s management team and more than 75% of Acorda’s associates. I can tell you that the interaction between Walk MS participants and Acorda employees who staffed our booth was powerful and unlike any I have seen or heard of between a pharmaceutical company and the public. I believe that this uniquely personal and committed approach differentiates Acorda as a biopharmaceutical company that listens to its customers and works to be a valued partner to patients, their families, their physicians and other health care providers.

I am pleased that our shareholders remain committed to supporting our mission and appreciate the trust you have placed in us. Acorda demonstrated consistent achievement and growth in 2008, and we look forward to the opportunity to build on that success with you and for you in 2009 as we continue moving Fampridine-SR toward commercialization and our preclinical compounds toward the clinic.



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

“The first year we rolled out the *I Walk Because* program we didn’t know what to expect. The team was overwhelmed by the positive response of the MS community as well as the enthusiasm of the Acorda volunteers. I think we achieved our goal of giving the community a voice on the importance of walking.”
—Erica Wishner,
Fampridine-SR
Consumer
Marketing Team

leadership

contact

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