## 2018 ANNUAL REPORT





# LETTER FROM THE CEO

## **DEAR SHAREHOLDER:**

2018 closed with a major milestone for Acorda – on December 21, the U.S. Food and Drug Administration (FDA) approved INBRIJA™ (levodopa inhalation powder) for the intermittent treatment of OFF episodes (also known as OFF periods) in adults with Parkinson's disease treated with carbidopa/levodopa.

## INBRIJA - ADDRESSING AN IMPORTANT UNMET MEDICAL NEED IN THE PARKINSON'S COMMUNITY

Levodopa, INBRIJA's active ingredient, in combination with carbidopa, is widely considered the gold standard treatment for Parkinson's disease. OFF periods are the re-emergence of Parkinson's symptoms; variable absorption of levodopa in the gut, as well as the drug's short half-life, contribute to the development of OFF periods. OFF periods are considered among the most troubling unmet medical needs in Parkinson's, by both people with Parkinson's (PwPs) and their healthcare professionals. INBRIJA is the first and only inhaled levodopa for on-demand treatment of OFF periods, providing a significant new treatment option for the Parkinson's community.

At the end of February 2019, we announced the commercial availability of INBRIJA. Our sales force is now calling on movement disorder specialists, and our market access and medical teams are meeting with managed care and payor groups to educate them about INBRIJA's clinical profile. The feedback from healthcare professionals, patient advocacy organizations and the patient community has been enthusiastic. As is typical in a launch year, we do not intend to provide revenue guidance for INBRIJA in 2019, but plan to provide our shareholders with other metrics to aid in evaluating the progress of the launch.



We estimate that approximately 350,000 PwPs in the U.S. currently experience OFF periods while on a carbidopa/levodopa regimen. We believe that peak sales of INBRIJA in the U.S. will exceed \$800 million.

We submitted a Marketing Authorization Application (MAA) for INBRIJA to the European Medicines Agency (EMA) in March 2018 and expect a final decision from the European Commission before the end of 2019. We plan to seek a partner for the commercialization of INBRIJA in Europe and Japan.

In September 2018, by a 2-1 vote, the United States Court of Appeals for the Federal Circuit upheld the District Court's decision to invalidate our patents for AMPYRA®, allowing generic manufacturers to enter the market. We disagree with the ruling, which we believe also has broad negative implications for biopharmaceutical innovation, and we have filed an appeal with the Supreme Court. We continue to market branded AMPYRA so that it remains available to the patients who rely on it. In 2018, AMPYRA reported net revenue of \$455 million. However, revenues have declined significantly since September 2018, and we expect continued declines as additional generics enter the market. Therefore, we are not providing AMPYRA revenue guidance for 2019

We ended the year with approximately \$445 million on our balance sheet. This was a result of executing on our detailed contingency plans: monetizing non-strategic assets, maximizing AMPYRA revenue and remaining fiscally disciplined. We believe this cash is adequate for the Company to become cash flow positive, based on our long-range projections.

## LEVERAGING OUR LEADING SPECIALTY SALES AND MARKETING ORGANIZATION

Acorda has developed one of the most effective and experienced specialty sales teams in the U.S., with an average of 18 years in the pharmaceutical industry. We believe that our successful neurology commercial experience and infrastructure position us well for a successful launch of INBRIJA. Our field sales and medical teams are trained and we have launched a full suite of in-office and digital educational materials, enabling a variety of opportunities for healthcare professionals and PwPs to learn about INBRIJA.

We are distributing INBRIJA via a closed network of specialty pharmacies. All prescriptions are triaged by our Prescription Support Services center. A customer service representative connects with each patient, performs an individualized benefits investigation, and speaks directly to the patient regarding the cost of their prescription and the support that we are providing them.

### LEADERSHIP IN THE PARKINSON'S COMMUNITY

A significant feature of Acorda's "brand" is the personal attention and support we provide to the patient communities affected by our products. As we did previously with the MS community, we have established close partnerships

with Parkinson's patient advocacy organizations and with individual PwPs and their families. Our disease state Facebook page, The Many Faces of OFF®, has over 106,000 followers, making it the largest industry-sponsored Facebook site for Parkinson's. We have also seen a progressive increase in engagement on this site among the Parkinson's community, where it has become a source of peer-to-peer encouragement and support.

Our consumer education program, "Live Well. Do Tell." provides wellness programming for the Parkinson's community. We periodically convene an advisory board comprising all four "pillars" of the community: healthcare professionals, patient advocacy organizations, PwPs and care partners. In 2018, based on the advisory board's recommendation, we launched *Framing OFF Through Art* "M, which uses custom works of art to share a PwP's experience of living with OFF periods.

### **ARCUS**

Our proprietary ARCUS® drug delivery technology began in the laboratory of Dr. Robert S. Langer of the Massachusetts Institute of Technology. ARCUS transforms medicines into light, dry powders and allows higher doses of medication to be delivered via inhalation, versus traditional dry powder inhalers. This technology has the potential to deliver inhaled medicines for a variety of both systemic and pulmonary conditions

We believe ARCUS will be an important platform for our future growth and we are working to identify a target in migraine appropriate for development for inhalation. We are also working with the Bill & Melinda Gates Foundation to develop a dry powder version of lung surfactant, a treatment for neonatal respiratory distress syndrome. While this program is aimed primarily at developing a product for use in developing countries, we believe it also will help us to adapt ARCUS for commercial pediatric uses.

## **2019 PRIORITIES**

- Successful U.S. launch and commercialization of INBRIJA
- Identify and advance a pipeline candidate for the use of ARCUS in migraine
- Maintain a strong balance sheet

On behalf of our Leadership Team, Board of Directors and our associates, thank you, our shareholders, for your continued support. We look forward to building on the successes of 2018 to deliver substantial shareholder value in 2019.

RON COHEN, M.D.
PRESIDENT AND CEO

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## NOW AVAILABLE



On December 21, 2018, the FDA approved INBRIJA for the intermittent treatment of OFF episodes, also known as OFF periods, in adults with Parkinson's disease taking carbidopa/levodopa.

On February 28, 2019, Acorda announced its commercial launch. INBRIJA is an inhaled form of levodopa, the gold standard for the treatment of Parkinson's, based on the innovative ARCUS® technology.

Despite being on treatment, patients may experience OFF periods as their Parkinson's progresses, which can be disruptive. Acorda estimates that 350,000 people in the U.S. are currently on a carbidopa/levodopa regimen and experience OFF periods and believes that peak sales of INBRIJA in the U.S. will exceed \$800 million.

Information about INBRIJA can be found at www.inbrija.com



## PARKINSON'S COMMUNITY

## FRAMING OFF THROUGH ART<sup>SM</sup>

Framing OFF Through Art uses the power of art to illustrate how OFF periods impact those living with Parkinson's, and to encourage people with Parkinson's to recognize their OFF symptoms and communicate them to their care partner and healthcare professionals. This initiative builds on Acorda's "Live Well. Do Tell.®" program, which we launched in March 2018. Each work of art is inspired by the personal story of a person with Parkinson's and their care partner, and in collaboration with an artist who has their own connection to Parkinson's.





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The art created for Framing OFF Through Art can be found at

www.livewelldotell.org

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## 2018 HIGHLIGHTS







\$445 M

OUR MISSION IS TO DEVELOP THERAPIES THAT RESTORE FUNCTION AND IMPROVE THE LIVES OF PEOPLE WITH NEUROLOGICAL DISORDERS.

The workplace environment created by our associates has received national and local recognition. Our culture of integrity, collaboration, and open communication is critical to advancing our mission to develop therapies that improve the lives of people with neurological disorders.



## MANAGEMENT

## **LEADERSHIP TEAM**

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

**Burkhard Blank, M.D.**Chief Medical Officer
and Head of R&D

**Peter S. Carbone** Senior Vice President, Quality

**Denise Duca, Ed.M.**Executive Vice President,
Human Resources

**Andrew A. Hindman** *Chief Business Officer* 

**David Lawrence, M.B.A.**Chief, Business Operations

Chief, Business Operations and Principal Accounting Officer

**Lauren Sabella**Chief Commercial Officer

**Tierney Saccavino**Executive Vice President,
Corporate Communications

Jane Wasman, J.D. President, International and General Counsel

## **BOARD OF DIRECTORS**

Ron Cohen, M.D. Founder

**Barry Greene**Board Member since 2007

Peder K. Jensen, M.D. Board Member since 2011

**John P. Kelley**Board Member since 2008

**Sandra Panem, Ph.D.**Board Member since 1998

**Lorin J. Randall**Board Member since 2006

**Steven M. Rauscher** *Board Member since 2005* 

Catherine D. Strader, Ph.D. Board Member since 2017

