



**LIFE.
SCIENCE.**

2015 ANNUAL REPORT

DEAR MEMBERS OF THE ACORDA COMMUNITY:



We aim to grow Acorda into the preeminent biopharmaceutical company delivering innovative therapies for people with neurological disorders, and are building on three pillars to drive long-term value creation:

- 1 Advancing our diversified clinical pipeline to approval and commercialization;
- 2 Acquiring assets that leverage our core competencies in neurology; and
- 3 Continuing to grow sales in multiple sclerosis of AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg.

We have made progress in all three areas since our last annual report. We:

- ✓ Announced the **acquisition of Biotie Therapies** in January 2016. Key to this transaction are global rights to two clinical-stage Parkinson's disease (PD) programs, which would complement our late-stage PD program, CVT-301.
- ✓ Continued to advance our leading innovative neurology pipeline. Pending the close of the Biotie transaction, we will have **eight clinical-stage assets** — including four in Phase 3, two in Phase 2 and two in Phase 1. **With positive clinical trial data, we potentially will be able to submit New Drug Applications for three of our pipeline therapies — PLUMIAZ™ (diazepam) Nasal Spray, CVT-301 and tozadenant — by the end of 2018.** We project these products, if approved, could have combined U.S. peak sales of over \$1 billion.
- ✓ **Successfully completed our first early-stage clinical study for CVT-427** in migraine and **continued to enroll participants in our second Phase 1 study for rHlgM22** in MS.
- ✓ **Achieved AMPYRA net revenue of \$437 million in 2015, a 19% increase over 2014.** We are projecting continued growth in 2016, guiding to net sales of \$475-\$485 million.

TRANSFORMING OUR PIPELINE

Acorda's early history was defined by our efforts to develop and commercialize AMPYRA, which has become a standard of care for people with multiple sclerosis (MS) who experience MS-related walking difficulty. Over the past 24 months, we have dramatically enhanced our company's profile.

Our acquisition of Civitas Therapeutics in late 2014 added CVT-301, a highly promising therapy currently in Phase 3 development for treating OFF periods in people with Parkinson's disease. In addition, this transaction brought to Acorda the novel ARCUS® inhaled dry powder technology platform, and a commercial-scale manufacturing facility for ARCUS-based products. ARCUS has shown the ability to deliver medication rapidly into the bloodstream, in much larger doses than other inhalation technologies. The ARCUS platform already has yielded a second pipeline product, CVT-427, an inhaled zolmitriptan formulation aimed at acute treatment of migraine, and has the potential to deliver others. We plan to initiate additional CVT-427 studies later this year.

Our acquisition of Biotie Therapies, which we expect to complete in the second half of 2016, adds two Parkinson's disease therapies to our pipeline that are complementary to CVT-301. One of these, tozadenant, is in Phase 3 clinical development.

LATE-STAGE PIPELINE: MULTIPLE NEAR-TERM MILESTONES

We anticipate milestones in the next 6-12 months for three of our late-stage programs:

- ✓ **CVT-301:** We expect to achieve the “last patient out” milestone in the pivotal Phase 3 clinical trial by the end of 2016. If successful, we plan to file a New Drug Application (NDA) in the first quarter of 2017.
- ✓ **PLUMIAZ™ (diazepam):** We are advancing the clinical work necessary to refile an NDA for PLUMIAZ and anticipate submitting the NDA in Q1 2017.
- ✓ **Dalfampridine for Post-Stroke Walking Difficulty (PSWD):**
 - At the end of Q1 2016, we announced the completion of our single-dose pharmacokinetic (PK) studies of three different once-daily (QD) formulations of dalfampridine. Results for at least one of these formulations met our criteria. The multi-dose phase of PK testing will begin in the second quarter of 2016.
 - Given our progress in the development of a QD formulation, we made the decision to stop enrollment of the Phase 3 clinical trial and conduct an unblinded analysis of the data, having reached 50% of its target enrollment in the study, or 270 subjects. Data are expected by the fourth quarter of 2016 and will be used to inform the design of planned Phase 3 trials.

EARLIER-STAGE PROGRAM UPDATES

- ✓ **rHlgM22:** We began a second Phase 1 clinical trial for remyelination in MS, following successful completion of a Phase 1 trial in 2014. We presented the results of the first Phase 1 trial at the 2015 American Academy of Neurology (AAN) and European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) annual meetings.
- ✓ **CVT-427:** This program uses the ARCUS technology to deliver doses of zolmitriptan from the lungs directly to the bloodstream. Results of our Phase 1 PK trial met our specifications, and we plan to continue clinical development of CVT-427.
- ✓ **Cimaglermin alfa:** The program for heart failure was put on clinical hold following a safety report of hepatotoxicity in our second Phase 1 clinical trial. There was a similar report in the first cimaglermin trial. We are working with outside experts to better understand this liver effect and to assess next steps for this program.

AMPYRA® (DALFAMPRIDINE) INTELLECTUAL PROPERTY

As expected, generics companies have challenged our AMPYRA patents. We have five Orange Book-listed patents on AMPYRA that extend through 2027. Our outstanding in-house Legal team, together with experienced outside counsel, are vigorously defending our intellectual property. We have settled with four of the ten entities that submitted Abbreviated New Drug Applications (ANDA) for AMPYRA, granting them the right to launch generic dalfampridine tablets on a designated date in 2027, or potentially earlier under certain circumstances. A patent infringement litigation hearing with the remaining ANDA filers is scheduled to begin in federal district court in September.

Our legal team achieved a significant victory in a case against Mylan Laboratories, which had sought to litigate our patent case in its home state of West Virginia. The Federal Circuit Court of Appeals upheld the lower court’s verdict permitting the case to proceed in the District Court of Delaware, along with the other ANDA cases. Mylan has petitioned the Federal Circuit for a rehearing *en banc*, which we are now opposing.

Four of our Orange Book patents are also being challenged in a separate, relatively new U.S. Patent and Trademark Office process called *Inter Partes Review* (IPR). In 2015, the Patent Trial and Appeal Board (PTAB) rejected IPR filings by a hedge fund against two of our AMPYRA patents. In March 2016, the PTAB instituted four IPRs that were filed subsequently by the same hedge fund. We will litigate vigorously before the PTAB to defend our patents and anticipate a ruling on these IPR petitions by March 2017.

LOOKING AHEAD

Our top priorities for 2016-2017 are 1) execution of our late-stage CVT-301 and PLUMIAZ clinical trials, and the subsequent preparation and filing of regulatory submissions; 2) planning for commercialization of these therapies; 3) conducting an unblinded analysis of the BID dalfampridine post-stroke walking difficulty trial and completion of ongoing QD formulation development for use in future planned studies; 4) completion of the Biotie acquisition, integration of Biotie employees and execution of ongoing clinical programs; and 5) defending our intellectual property rights for AMPYRA.

Over the past two years, with the acquisitions of Civitas and Biotie, we have evolved Acorda into a company that is poised to make major contributions to the treatment of people with neurological disorders and deliver significant shareholder value. Diversification has been a key pillar of our growth strategy. All biopharma companies face repeated challenges and risks in their clinical, regulatory and intellectual property endeavors. Success ultimately depends on having enough high-quality “shots on goal,” in addition to outstanding personnel and supportive shareholders who are willing to take the long view. On behalf of our Management Team, Board of Directors and our passionate team of more than 500 Acordans, thank you, our shareholders, for your support in helping us build a great enterprise at Acorda.

I look forward to updating you on our progress.



Ron Cohen, M.D.
President and CEO

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

**LIFE-
SCIENCE.**

PIPELINE

THERAPY	INDICATION	PHASE 1	PHASE 2	PHASE 3
PLUMIAZ™ (Diazepam) Nasal Spray	Seizure Clusters			
CVT-301	Parkinson's Disease			
TOZADENANT (SYN115)*	Parkinson's Disease			
DALFAMPRIDINE	Chronic Post-Stroke Walking Difficulty			
SYN120*	Parkinson's Disease			
BTT1023*	Primary Sclerosing Cholangitis (PSC)			
CVT-427	Migraine			
rHlgM22	MS			

Acorda has a leading pipeline of novel neurological therapies addressing a range of disorders, including Parkinson's disease, epilepsy, post-stroke walking difficulty, migraine, and multiple sclerosis.

Pending the completion of our acquisition of Biotie, we will add three additional clinical-stage programs — including Phase 3 and Phase 2 compounds for the treatment of Parkinson's disease. Combined with our CVT-301 program, we will be positioned to become a leader in Parkinson's disease therapeutic development and commercialization.



ARCUS[®] TECHNOLOGY

We secured global rights to the proprietary ARCUS technology platform as part of our acquisition of Civitas Therapeutics in 2014. We are excited about the potential application of this technology to a broad range of therapies. Most importantly, the Civitas team has been a tremendous addition to our company, providing expertise on ARCUS and the clinical trial programs utilizing this technology. Many of these Acordans have been working with the ARCUS technology for over twenty years.

ARCUS is an investigational dry powder pulmonary delivery system that has potential applications in multiple disease areas. This platform is being studied to deliver significantly larger doses of medication than are possible with conventional dry powder formulations. Currently, we have two clinical-stage programs utilizing the ARCUS platform: CVT-301 and CVT-427.

The ARCUS inhaler is breath-actuated, operated by the user putting their lips to the device and simply breathing in.

Based on research and discoveries at the Massachusetts Institute of Technology (MIT) and Pennsylvania State University, the ARCUS technology has been used to successfully deliver more than one million doses to patients in clinical trials of various therapeutic agents. Our Chief Technology Officer, Dr. Rick Batycky, was one of the original members of the team that developed this technology.

Construction of our laboratory and commercial manufacturing facility in Chelsea, MA was completed in 2003. Many of our current colleagues contributed to the planning and design of the facility.

Investigational products CVT-301 and CVT-427 use the ARCUS technology as a delivery method for established, standard-of-care oral medications. We are also exploring additional development opportunities that may leverage the ARCUS technology.



In 2015, the Bill & Melinda Gates Foundation awarded Acorda a \$1.4 million grant to explore development of a formulation and delivery system for a dry powder version of lung surfactant, a drug used to treat respiratory distress syndrome (RDS) in newborns. The formulation, based on the ARCUS technology, is being developed in collaboration with MIT. RDS can be fatal, and the program objective is to increase access to appropriate care in developing countries.

BIOTIE ACQUISITION

In January 2016, we announced an agreement to acquire Biotie Therapeutics for approximately \$363 million in cash. This transaction, when completed, will add promising assets to our clinical pipeline and represents a significant opportunity to create shareholder value. The acquisition, which positions us to become a leader in developing novel therapies for Parkinson's disease, includes:

- ✓ Worldwide rights to tozadenant, an oral adenosine A_{2a} receptor antagonist currently in Phase 3 development to reduce daily OFF time for people with Parkinson's disease. If approved, adenosine A_{2a} receptor antagonists would be the first new class of therapy for the treatment of Parkinson's disease in the U.S. in more than 20 years. We are targeting an NDA filing for tozadenant by the end of 2018.
- ✓ Further expanding our Parkinson's disease therapeutics pipeline, we will also obtain global rights to SYN120, an oral, 5-HT₆/5-HT_{2A} dual receptor antagonist for treatment of Parkinson's-related dementia, in Phase 2 development with support from the Michael J. Fox Foundation.
- ✓ In addition, we will receive rights to two other assets:
 1. Selincro® (nalmefene), an opioid receptor antagonist marketed by H. Lundbeck A/S in the EU to reduce alcohol consumption in patients with alcohol dependence. We will receive a low double digit royalty on net sales.
 2. BTT1023, an early stage antibody candidate against VAP-1, a promising target for treatment of primary sclerosing cholangitis (PSC). An open-label, proof-of-concept study is currently enrolling. As liver disease is not a core focus, we expect to explore partnership opportunities for this asset.

The Biotie team has done a remarkable job in developing these clinical programs. Following the close of the acquisition, we plan to maintain the Biotie operation in San Francisco and retain staff at that site. We are considering the long-term future of the Biotie office in Turku, Finland.


We believe tozadenant and SYN120 are highly complementary to CVT-301, our existing Phase 3 Parkinson's disease program. CVT-301 is being studied to restore motor function when OFF periods occur, whereas tozadenant is being developed to reduce overall OFF time during the day in combination with current oral treatment regimens. SYN120, for Parkinson's-related dementia, is a novel compound that could benefit people with more advanced disease.

If approved, tozadenant would offer significant synergies with our outstanding neurology commercial organization. We anticipate an incremental expansion of our existing commercial infrastructure and sales force if CVT-301 is approved; no further significant expansion would then be necessary to accommodate commercialization of tozadenant. We estimate U.S. peak annual net revenue of tozadenant of more than \$400 million, and patent protection through 2025 with a potential patent term extension to 2030.

Combined with our other late-stage assets (CVT-301 and PLUMIAZ™ (diazepam)), we have the potential to launch three therapies in the U.S. by 2019 with projected U.S. peak sales of more than \$1 billion.

We anticipate that this transaction will be completed in the second half of 2016.

2016 GUIDANCE



AMPYRA[®]
(dalfampridine)
\$475-\$485M
IN NET SALES

- AMPYRA has shown steady growth since launch in 2010; 2016 guidance represents ~10% increase over 2015 sales.



R&D
\$165-\$175M*

- We are conducting registrational clinical trials for CVT-301 and PLUMIAZ™ (diazepam) and plan to submit U.S. regulatory filings for both compounds in 2017. An unblinded analysis of data from the Phase 3 twice-daily (BID) dalfampridine post-stroke walking difficulty trial, along with results from our QD formulation work, will inform next steps for this program.
- We are advancing earlier-stage clinical programs CVT-427 for acute treatment of migraine and rHlgM22 for remyelination in MS.



SG&A
\$195-\$205M*

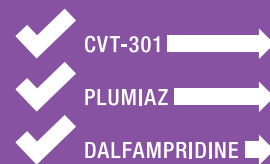
- Our infrastructure currently supports three commercial products, five clinical programs (including registration trials for CVT-301, PLUMIAZ and dalfampridine), and ARCUS® manufacturing capability in our Chelsea facility.



2015 HIGHLIGHTS



AMPYRA NET SALES
\$437M
19% GROWTH FROM 2014



ADVANCED LATE-STAGE CLINICAL TRIALS

CVT-301 FOR PARKINSON'S DISEASE
PLUMIAZ FOR SEIZURE CLUSTERS
DALFAMPRIDINE FOR POST-STROKE WALKING DIFFICULTY



POSITIVE SAFETY DATA
PHASE 1 CLINICAL TRIAL
rHlgM22
FOR REMYELINATION IN MS
INITIATED SECOND PHASE 1 STUDY



INITIATED AND COMPLETED
PHASE 1 TRIAL
CVT-427
IN DEVELOPMENT FOR ACUTE TREATMENT OF MIGRAINE

* excludes share-based compensation

WE FOUNDED ACORDA TO BRING LIFE-CHANGING THERAPIES TO PEOPLE LIVING WITH A WIDE RANGE OF NERVOUS SYSTEM DISORDERS.





ACCORDA[®]
THERAPEUTICS



OUR SUCCESS IS ROOTED IN THE CLOSE COLLABORATION OF A HIGHLY-SKILLED, DIVERSE AND MOTIVATED TEAM.



MANAGEMENT TEAM

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

Richard P. Batycky, Ph.D.
*Chief Technology Officer
and Site Head*

Andrew R. Blight, Ph.D.
Chief Scientific Officer

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

Andrew A. Hindman
Chief Business Development Officer

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

Michael Rogers
Chief Financial Officer

Lauren Sabella
Chief Commercial Officer

Tierney Saccavino
*Executive Vice President,
Corporate Communications*

Jane Wasman, J.D.
*President, International &
General Counsel*

BOARD OF DIRECTORS

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Board Member since 2011

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ACORDA[®]
T H E R A P E U T I C S

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