



LIFE.  
SCIENCE.

2016 ANNUAL REPORT



# LETTER FROM THE CEO

Dear Shareholder:

*In 2014, we began charting a course for the next stage of Acorda's growth, seeking to identify and acquire promising late-stage therapeutic candidates outside the company to bolster our internal development activities. These actions were important to accelerate the pursuit of our mission while improving the opportunity to generate long-term value for our shareholders.*

Ron Cohen, M.D.  
President and CEO



As a result of this new strategy, Acorda successfully acquired two companies with late-stage programs in Parkinson's disease: Civitas Therapeutics in the fall of 2014 and Biotie Therapies in early 2016. If successful, the key programs from these acquisitions, CVT-301 and tozadenant, will serve as the foundation for Acorda's future value and position the Company as a leader in the treatment of Parkinson's disease. Parkinson's affects more than one million Americans and between 7 million and 10 million people around the world. We are excited by the potential for CVT-301 and tozadenant to address unmet needs in the Parkinson's community.

In 2016, we focused on advancing these newly acquired late-stage Parkinson's disease programs. Our acquisition strategy has begun to deliver results, most recently with the positive efficacy and safety data from Phase 3 pivotal and long-term safety trials of CVT-301 that will support our upcoming New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA). If approved, we believe CVT-301 likely will become a key therapeutic

option for people with Parkinson's experiencing highly disruptive and sometimes unexpected OFF periods in their daily lives.

As we evolve toward Acorda's future in Parkinson's disease, we acknowledge the challenges we are experiencing: the failures of two of our development programs (PLUMIAZ and dalfampridine-SR for post-stroke walking difficulties) and a significant setback for AMPYRA, which has enabled the Company's historical growth. A U.S. District Court invalidated four patents that would have preserved market exclusivity for AMPYRA into the next decade. While we strongly disagree with the Court's ruling and will appeal the decision, we are prepared should we ultimately lose market exclusivity for AMPYRA in July 2018. We already have acted decisively to reduce expenses, downsizing the Company within days of the Court's ruling. Restructuring was painful, yet a necessary step to ensure that we focus resources on bringing our Parkinson's disease candidates to the marketplace.

We anticipate the following milestones in the next 12 months:

- CVT-301: We plan to submit an NDA to the FDA in the second quarter of 2017. We believe CVT-301 has the potential to achieve at least \$500 million in annual net sales in the U.S. We also plan to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) by year-end.
- Tozadenant: An oral adenosine A2a antagonist, tozadenant represents a potential first-in-class treatment for Parkinson's disease in the U.S. Phase 2b data showed its potential to lower average daily OFF time by more than an hour relative to placebo, in people already being treated with multiple other medications. We expect results from our pivotal Phase 3 clinical trial in Q1 2018. As part of the Phase 3 program, we also initiated an open-label, long-term safety study in the second quarter of 2017. We believe that tozadenant, if approved, represents a commercial opportunity that could exceed that for CVT-301.

Our top priorities are:

- 1) submitting an NDA for CVT-301 in Q2 2017;
- 2) submitting an MAA to the EMA for CVT-301 by the end of 2017;
- 3) planning for commercialization and launch of CVT-301 in the U.S.; and
- 4) executing the ongoing tozadenant clinical program, with pivotal efficacy data expected in Q1 2018.

On behalf of our Management Team, Board of Directors and our associates: thank you, our shareholders, for your continued support. Our focus to deliver both promising therapies and shareholder value has only sharpened over the past few months and we look forward to sharing with you the significant opportunities that lie ahead.

Ron Cohen, M.D.  
President and CEO



# ACORDA BUSINESS HIGHLIGHTS IN 2016 AND EARLY 2017

## AMPYRA

- U.S. District Court in Delaware ruled in March 2017 that four of Acorda's patents (8,663,685, 8,440,703, 8,354,437, and 8,007,826) were **invalid**, while upholding a fifth patent (5,540,938) expiring July 30, 2018. Acorda is appealing the District Court decision. If this appeal is unsuccessful, AMPYRA will lose market exclusivity after July 30, 2018.
- **AMPYRA net revenue was \$493 million in 2016, a 13% increase over 2015.** We are projecting continued growth in 2017, guiding to net sales of \$535-\$545 million.

## CORPORATE RESTRUCTURING

- **As a result of the District Court's decision on our AMPYRA patents, we implemented a headcount reduction of approximately 20% in April 2017.** We expect to realize estimated annualized cost savings of approximately \$21 million beginning in the second quarter of 2017.
- **In addition, R&D and SG&A expenses will be reduced.** Further details will be provided in our Q1 investor update.

## BUSINESS DEVELOPMENT

- **We completed the acquisition of Biotie Therapies**, which included global rights to two clinical-stage Parkinson's disease programs. Tozadenant, a selective adenosine A2a antagonist, is being developed to reduce daily average OFF time in people with Parkinson's.

## CLINICAL DEVELOPMENT

- **Received Phase 3 data for CVT-301.** Based on positive efficacy data announced in February 2017, coupled with data from two long-term safety studies, we are planning to file an NDA for CVT-301 by the end of Q2 2017. Pending FDA review and approval, we are planning for a potential commercial launch of this product in 2018.
- **CVT-427**, an inhaled formulation of zolmitriptan for acute migraine, showed favorable results in a pharmacokinetic Phase I study. Some asthmatic subjects showed evidence of acute, reversible bronchoconstriction in a subsequent special population study, which we are evaluating.
- **Discontinued two late-stage clinical programs.** Results from clinical trials of PLUMIAZ for cluster seizures in epilepsy and dalfampridine-SR for treatment of post-stroke walking difficulties did not show the pharmacokinetic profile and sufficient efficacy needed to advance these programs.



## Exploring partnerships for early stage programs:

- SYN120, a 5-HT6/2A dual antagonist, is being studied in a Phase 2 clinical trial in Parkinson's disease-related dementia. We expect this study to be completed in the first half of 2018.
- rHlgM22 is currently in a Phase 1 clinical trial for remyelination in multiple sclerosis, which we expect to complete in the second half of 2017.
- Cimaglermin alfa for the treatment of heart failure was put on clinical hold following a safety report of hepatotoxicity in our second Phase 1 clinical trial.

## MANUFACTURING

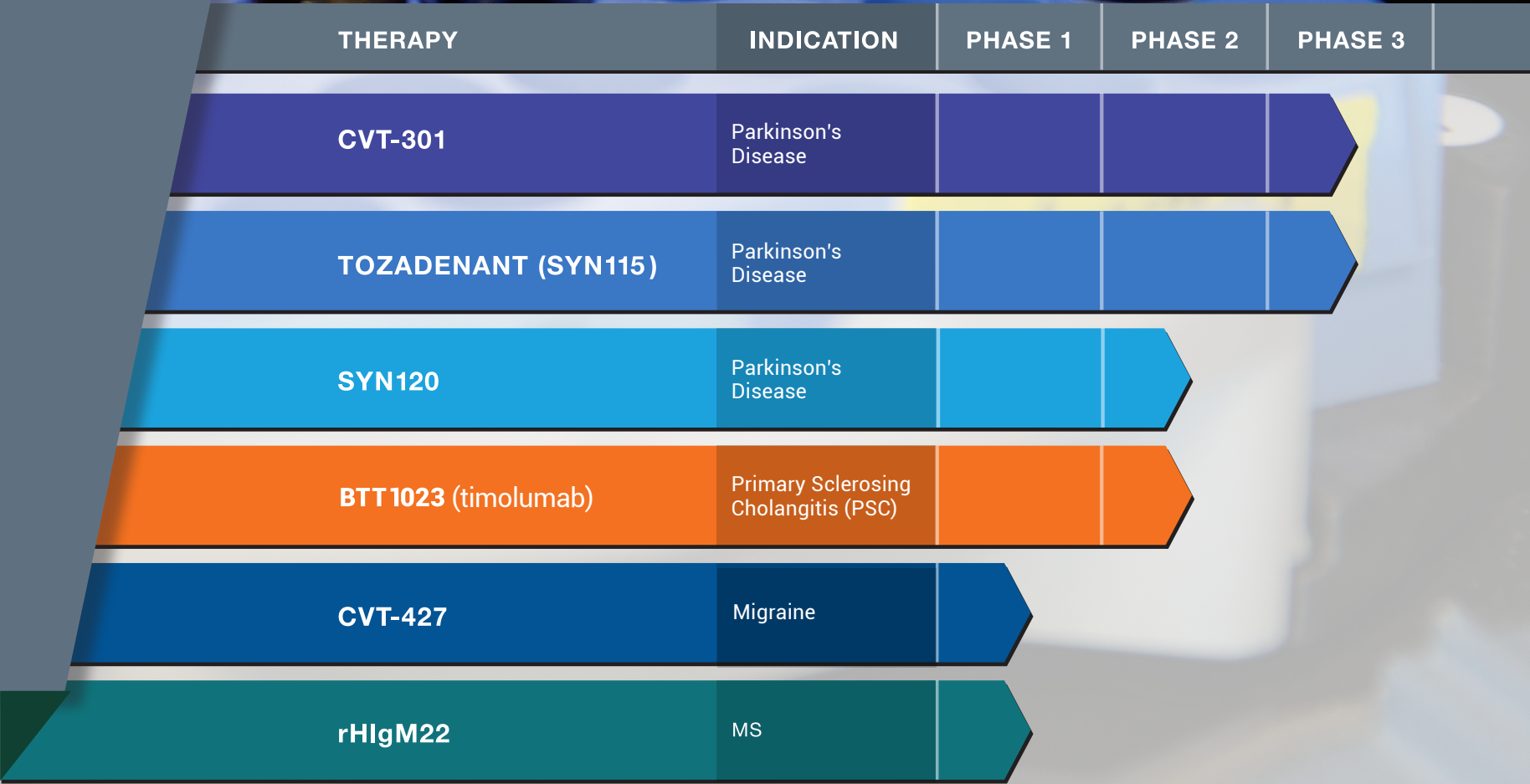
- **Converted Acorda's Chelsea location to a dedicated manufacturing site in preparation for potential regulatory approval of CVT-301.** Non-manufacturing activities were moved out of the Chelsea facility to minimize GMP compliance risks and support launch readiness. Non-301 activities were moved to a small satellite lab space located in Waltham, MA.
- **Manufacturing scale up continuing:** 2016 marked the shift to 24/7 manufacturing capabilities for CVT-301.



PIPELINE

Acorda has a leading pipeline of novel neurological therapies addressing a range of disorders, including Parkinson's disease (PD), migraine and multiple sclerosis.

With two late-stage programs exploring different treatment approaches to Parkinson's, we are positioned to become a leader in PD therapeutic development and commercialization. We plan to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for CVT-301 by June 2017, followed by a regulatory filing in Europe by the end of the year. We expect results from our pivotal Phase 3 clinical trial of tozadenant in Q1 2018.





## HIGHLIGHTS



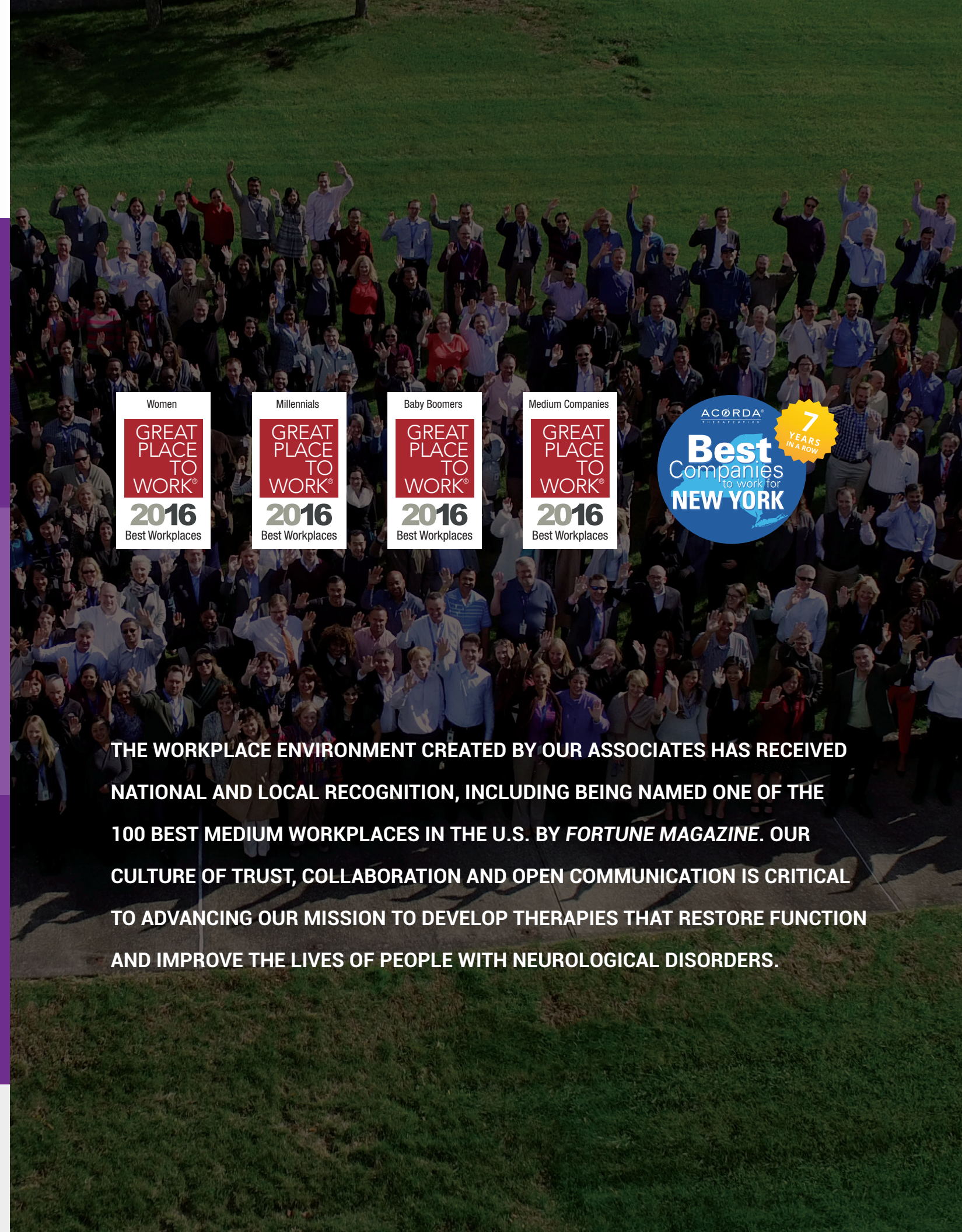
AMPYRA NET SALES  
**\$493 M**  
13% Growth from 2015



SUCCESSFUL COMPLETION OF  
**CVT-301**  
PHASE 3 PROGRAM  
FDA SUBMISSION TARGETED IN Q2 2017



ACQUIRED BIOTIE THERAPIES  
ADDED INVESTIGATIONAL THERAPIES  
**TOZADENANT, SYN120**  
AND **BTT1023** TO ACORDA PIPELINE



THE WORKPLACE ENVIRONMENT CREATED BY OUR ASSOCIATES HAS RECEIVED NATIONAL AND LOCAL RECOGNITION, INCLUDING BEING NAMED ONE OF THE 100 BEST MEDIUM WORKPLACES IN THE U.S. BY *FORTUNE* MAGAZINE. OUR CULTURE OF TRUST, COLLABORATION AND OPEN COMMUNICATION IS CRITICAL TO ADVANCING OUR MISSION TO DEVELOP THERAPIES THAT RESTORE FUNCTION AND IMPROVE THE LIVES OF PEOPLE WITH NEUROLOGICAL DISORDERS.



# MANAGEMENT

## MANAGEMENT TEAM

**Ron Cohen, M.D.**

*President and Chief Executive Officer*

**Richard P. Batycky, Ph.D.**

*Chief Technology Officer and Site Head*

**Burkhard Blank, M.D.**

*Chief Medical Officer*

**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, Business Operations and  
Principal Accounting Officer*

**Lauren Sabella**

*Chief Commercial Officer*

**Tierney Saccavino**

*Executive Vice President,  
Corporate Communications*

**Jane Wasman, J.D.**

*President, International &  
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*

**Ian F. Smith**

*Board Member since 2007*

**Catherine D. Strader, Ph.D.**

*Board Member since 2017*







**LIFE.  
SCIENCE.**

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