

# Regulatory Update on DRP sNDA

March 8, 2021

#### Forward-Looking Statements



This presentation contains forward-looking statements. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed in or implied by such forward-looking statements. Each of these statements is based only on current information, assumptions and expectations that are inherently subject to change and involve a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements about (i) plans for, including timing and progress of commercialization of, NUPLAZID® or for the clinical development of our product candidates, including pimavanserin and trofinetide; (ii) benefits to be derived from and efficacy of our product candidates, including the use of pimavanserin in dementia-related psychosis, schizophrenia or other neurological or psychiatric indications, potential advantages of NUPLAZID versus existing antipsychotics or antidepressants, and expansion opportunities for NUPLAZID; (iii) estimates regarding the prevalence of Parkinson's disease psychosis, dementia-related psychosis, schizophrenia and the potential use of trofinetide in Rett syndrome; (iv) potential markets for any of our products, including NUPLAZID and trofinetide; (v) our estimates regarding our future financial performance, cash position or capital requirements; and (vi) currently anticipated impacts of COVID-19 on Acadia's business, including its commercial sales operations, current and planned clinical trials, supply chain, and guidance for full-year 2021 NUPLAZID net sales and certain expense line items.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions (including the negative thereof) intended to identify forward-looking statements. Given the risks and uncertainties, you should not place undue reliance on these forward-looking statements. For a discussion of the risks and other factors that may cause our actual results, performance or achievements to differ, please refer to our annual report on Form 10-K for the year ended December 31, 2020 as well as our subsequent filings with the SEC. The forward-looking statements contained herein are made as of the date hereof, and we undertake no obligation to update them for future events.



## **Opening Remarks**

**Steve Davis** 

**Chief Executive Officer** 

### Pimavanserin DRP sNDA: Summary of FDA Correspondence



June, 2020: Acadia submits sNDA

July, 2020: FDA accepted sNDA for filing

FDA stated they identified no potential review issues

FDA stated they are not planning to hold an Advisory Committee

November, 2020: FDA's mid-cycle review meeting

December, 2020: FDA mid-cycle communication to Acadia

FDA stated they identified no review issues

FDA confirmed they are not planning to hold an Advisory Committee

February 11, 2021: Acadia inquired if FDA still on-track for communication of labeling on March 3, 2021

February 18, 2021: FDA stated they were on-track for communication around March 3rd

March 3, 2021: FDA notification that they identified deficiencies precluding labeling discussions

- FDA did not provide, and has not yet provided, any information on the nature of the deficiencies
- FDA stated that the notification does not reflect a final decision on the information under review

# ACADIA

**Q&A Session**