# Bristol Myers Squibb to Acquire Karuna Therapeutics

**December 22, 2023** 



### Forward Looking Statements

#### Additional Information and Where to Find it

In connection with the proposed acquisition of Karuna Therapeutics by Bristol Myers Squibb, Karuna Therapeutics intends to file a preliminary and definitive proxy statement. The definitive proxy statement and proxy card will be delivered to the stockholders of Karuna Therapeutics in advance of the special meeting relating to the proposed acquisition. This communication is not a substitute for the proxy statement or any other document that may be filed by Karuna Therapeutics with the SEC. KARUNA THERAPEUTICS' STOCKHOLDERS AND INVESTORS ARE URGED TO READ THE DEFINITIVE PROXY STATEMENT IN ITS ENTIRETY WHEN IT BECOMES AVAILABLE AND ANY OTHER DOCUMENTS FILED BY EACH OF BRISTOL MYERS SQUIBB AND KARUNA THERAPEUTICS WITH THE SEC IN CONNECTION WITH THE PROPOSED ACQUISITION OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED ACQUISITION AND THE PARTIES TO THE PROPOSED ACQUISITION. Investors and security holders will be able to obtain a free copy of the proxy statement and such other documents containing important information about Bristol Myers Squibb and Karuna Therapeutics, once such documents are filed with the SEC, through the website maintained by the SEC at www.sec.gov. Bristol Myers Squibb and Karuna Therapeutics make available free of charge at Bristol Myers Squibb's website at www.bms.com/investors and Karuna Therapeutics' website at https://karunatx.com/, respectively, copies of materials they file with, or furnish to, the SEC.

#### Participants in the Solicitation

This communication does not constitute a solicitation of a proxy, an offer to purchase or a solicitation of an offer to sell any securities. Bristol Myers Squibb, Karuna Therapeutics and their respective directors, executive officers and certain employees may be deemed to be participants in the solicitation of proxies from the stockholders of Karuna Therapeutics in connection with the proposed acquisition. Information regarding Bristol Myers Squibb's directors and executive officers is contained in Bristol Myers Squibb's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, which was filed with the SEC on February 14, 2023, and its definitive proxy statement for the 2023 annual meeting of stockholders, which was filed with the SEC on March 23, 2023. Information regarding Karuna Therapeutics' directors and executive officers is contained in Karuna Therapeutics' definitive proxy statement for the 2023 annual meeting of stockholders, which was filed with the SEC on April 27, 2023. To the extent holdings of Bristol Myers Squibb's or Karuna Therapeutics' securities by their respective directors or executive officers have changed since the amounts set forth in such 2023 proxy statements, such changes have been or will be reflected on Initial Statements of Beneficial Ownership on Form 4 filed with the SEC. Additional information regarding the identity of potential participants, and their direct or indirect interests, by security holdings or otherwise, will be included in the definitive proxy statement relating to the proposed acquisition when it is filed with the SEC. These documents (when available) may be obtained free of charge from the SEC's website at www.sec.gov, Bristol Myers Squibb's website at https://karunatx.com/.

#### **Cautionary Statement Regarding Forward-Looking Statements**

This communication contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, regarding, among other things, the proposed acquisition of Karuna Therapeutics by Bristol Myers Squibb, the expected timetable for completing the transaction, future opportunities for the combined businesses, the expected benefits of Bristol Myers Squibb's acquisition of Karuna Therapeutics and the development and commercialization of Karuna Therapeutics' product candidates, including the therapeutic and commercial potential of KarXT and Karuna Therapeutics' other technologies and products in development. These statements may be identified by the fact they use words such as "should," "could," "expect," "anticipate," "target," "may," "project," "guidance," "intend," "believe," "will" and other words and terms of similar meaning and expression in connection with any discussion of future operating or financial performance, although not all forward-looking statements contain such terms. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. These statements are only predictions, and such forward-looking statements are based on current expectations and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them, that are difficult to predict, may be beyond our control and could cause actual outcomes and results to differ materially from those expressed in, or implied by, the forward-looking statements. Actual results may differ materially because of numerous risks and uncertainties including with respect to (i) the approval of Karuna Therapeutics' stockholders of the proposed acquisition, which may be delayed or may not be obtained, (ii) the risk that the expected benefits or synergies of the acquisition will not be realized, (iii) the risk that legal proceedings may be instituted related to the merger agreement, (iv) any competing offers or acquisition proposals for Karuna Therapeutics, (v) the possibility that various conditions to the consummation of the acquisition may not be satisfied or waived, including that a governmental entity may prohibit, delay or refuse to grant approval for the acquisition and (vii) unanticipated difficulties or expenditures relating to the proposed acquisition, including the response of business partners and competitors to the announcement of the proposed acquisition or difficulties in employee retention as a result of the announcement and pendency of the proposed acquisition. The actual financial impact of this transaction may differ from the expected financial impact described in this communication, the compounds described in this communication are subject to all the risks inherent in the drug development process, and there can be no assurance that the development of these compounds will be commercially successful. No forward-looking statement can be guaranteed. Forward-looking statements in this communication should be evaluated together with the many risks and uncertainties that affect Bristol Myers Squibb's business and market, particularly those identified in the cautionary statement and risk factors discussion in Bristol Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2022, and Karuna Therapeutics' business, particularly those identified in the risk factors discussion in Karuna Therapeutics' Annual Report on Form 10-K for the year ended December 31, 2022, as well as other documents that may be filed by Bristol Myers Squibb or Karuna Therapeutics from time to time with the SEC. Neither Bristol Myers Squibb nor Karuna Therapeutics undertakes any obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. The forward-looking statements made in this communication relate only to events as of the date on which the statements are made and readers are cautioned not to place undue reliance on such statements.



### Non-GAAP Financial Information

#### Use of Non-GAAP Financial Information and Financial Guidance

In discussing financial guidance, Bristol Myers Squibb refers to financial measures that are not in accordance with U.S. Generally Accepted Accounting Principles (GAAP). The non-GAAP financial measures are provided as supplemental information to the financial measures presented in this communication that are calculated and presented in accordance with GAAP and are presented because management has evaluated the company's financial results both including and excluding the adjusted items or the effects of foreign currency translation, as applicable, and believes that the non-GAAP financial measures presented portray the results of the company's baseline performance, supplement or enhance management, analysts and investors overall understanding of the company's underlying financial performance and trends and facilitate comparisons among current, past and future periods.

Non-GAAP earnings and related EPS information are adjusted to exclude certain costs, expenses, gains and losses and other specified items that are evaluated on an individual basis after considering their quantitative and qualitative aspects and typically have one or more of the following characteristics, such as being highly variable, difficult to project, unusual in nature, significant to the results of a particular period or not indicative of past or future operating results. These items are excluded from non-GAAP earnings and related EPS information because Bristol Myers Squibb's business nor reflect Bristol Myers Squibb's underlying business performance. Similar charges or gains were recognized in prior periods and will likely reoccur in future periods.

Because the non-GAAP financial measures are not calculated in accordance with GAAP, they should not be considered superior to or as a substitute for the related financial measures that are prepared in accordance with GAAP and are not intended to be considered in isolation and may not be the same as or comparable to similarly titled measures presented by other companies due to possible differences in method and in the items being adjusted. We encourage investors to review our financial statements and publicly-filed reports in their entirety and not to rely on any single financial measure.

A reconciliation of the forward-looking non-GAAP measures presented in this communication is not provided due to the inherent difficulty in forecasting and quantifying items that are necessary for such reconciliation. Namely, we are not able to reliably predict the impact of specified items such as unwind of inventory purchase price adjustments, accelerated depreciation and impairment of property, plant and equipment and intangible assets and stock compensation resulting from acquisition-related equity awards, or currency exchange rates beyond the next twelve months. As a result, the reconciliation of these non-GAAP measures to the most directly comparable GAAP measures is not available without unreasonable effort. In addition, Bristol Myers Squibb believes such a reconciliation would imply a degree of precision and certainty that could be confusing to investors. The variability of the specified items may have a significant and unpredictable impact on our future GAAP results. In addition, the non-GAAP financial guidance in this communication excludes the impact of any potential additional future strategic acquisitions and divestitures and any specified items that have not yet been identified and quantified. The financial guidance is subject to risks and uncertainties applicable to all forward-looking statements as described elsewhere in this communication.



# Our overarching goal is to achieve sustainable, top-quartile growth



Increase company growth rate



Maximize potential of the internal portfolio and pipeline



Complement internal assets with disciplined business development

# Acquisition of Karuna expands and strengthens our presence in neuroscience while augmenting our growth profile









#### **Adds Lead Asset KarXT**

- Potential first-in-class treatment in schizophrenia and first-in-disease treatment in Alzheimer's disease psychosis (ADP)
- Antipsychotic with novel M1/M4 receptor agonism; U.S. PDUFA date late Q3 2024
- Compelling efficacy and differentiated safety
- Multi-billion-dollar peak sales opportunities across multiple indications



**Promising Early-Stage Opportunities** 

# Karuna accelerates the expansion and diversification of BMS's neuroscience portfolio

#### **BMS NEUROSCIENCE PORTFOLIO**

#### PHASE 1



- KAR-2618 (Mood/anxiety)
- Pre-Clinical Asset
  (confidential), Transitioning to
  Phase 1
- Other Early-Stage
  Opportunities

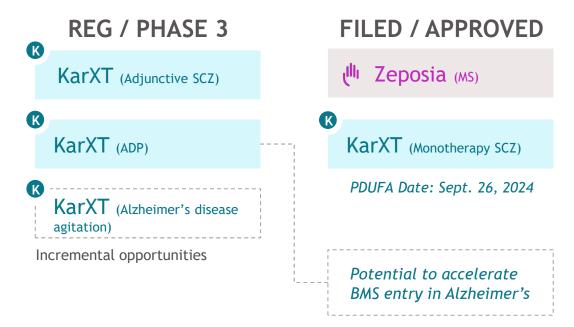
(Autism, depression, mania, anxiety, and migraine - across clinical and preclinical assets)

#### PHASE 2\*



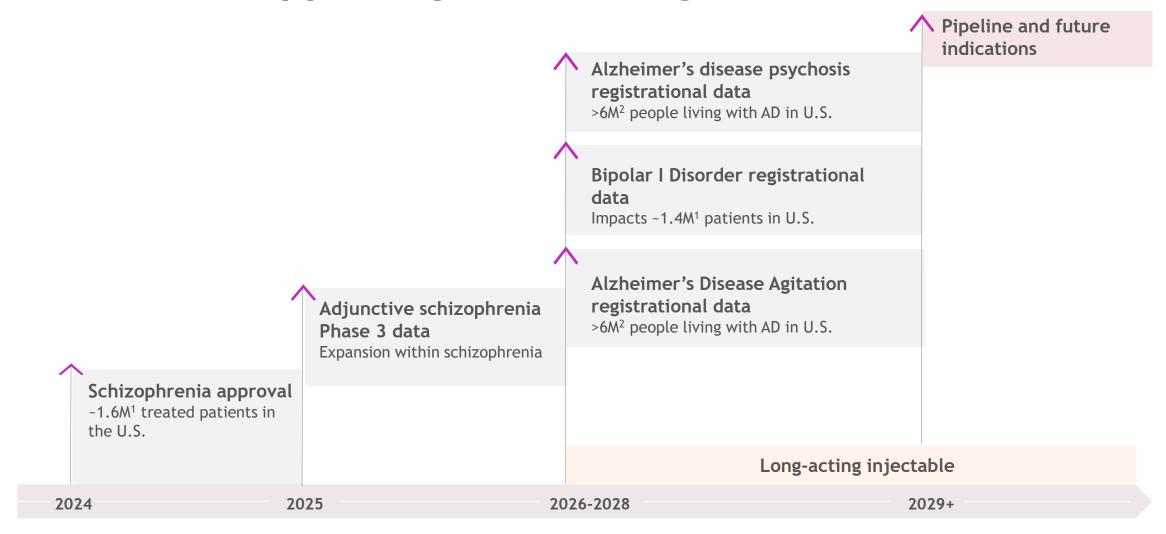
- elF2B (ALS and Alzheimer's disease)
- FAAH/MGLL (Other)
- KarXT (bipolar I disorder)

Incremental opportunities

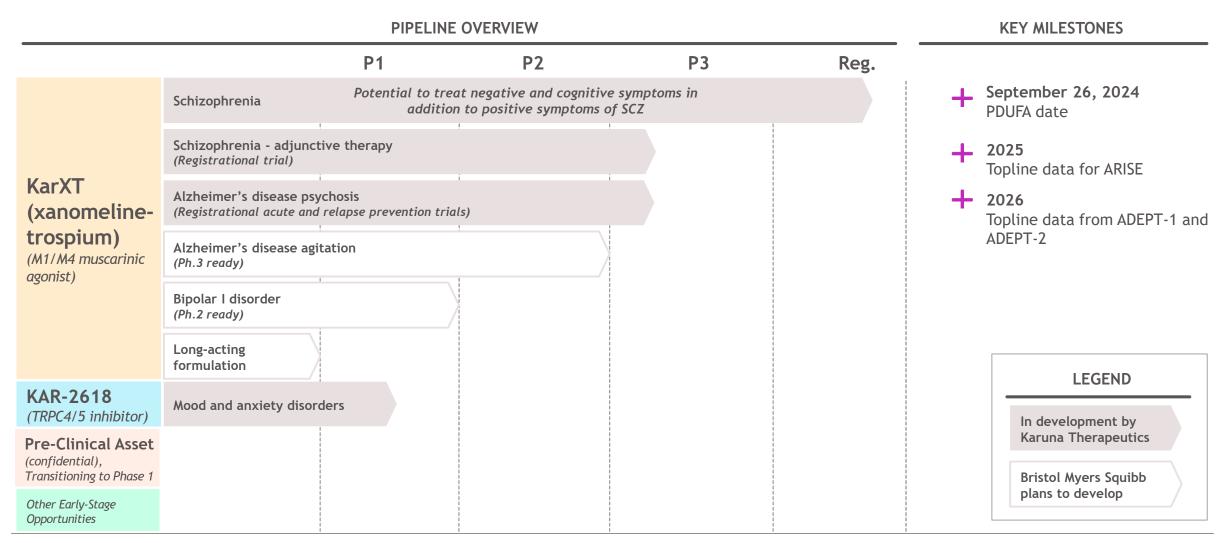




# KarXT: Starting next year, opportunity for series of indications supporting continued growth



### Karuna pipeline addresses neurological and psychiatric conditions

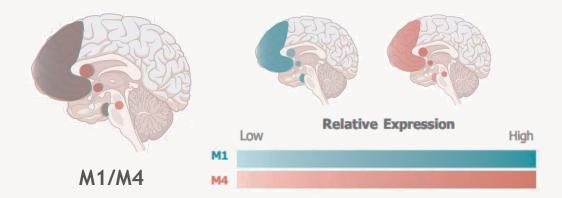


# KarXT: Potential first-in-class antipsychotic with unique MoA leading to differentiated efficacy and safety

#### **Unique 2-Drug Combination**

#### KarXT = Xanomeline + Trospium

- Xanomeline: Direct acting M1/M4 muscarinic agonist with potential to be effective in cholinergic deficient conditions
  - Acts directly at muscarinic receptors with potential advantages over acetylcholine requiring PAMs e.g. in Alzheimer's
  - M1 agonism alongside M4 activity in KarXT could uniquely improve cognitive functions
- Trospium: peripheral muscarinic antagonist to reduce side-effects



- + Compelling efficacy and safety in schizophrenia based on Phase 3 data
- + Expected launch in schizophrenia in late 2024
- + Complementary MoA and differentiated safety support potential to be first approved adjunctive treatment in schizophrenia
- Opportunity to be first agent approved in Alzheimer's Disease Psychosis
- Patent protection through mid-2030s

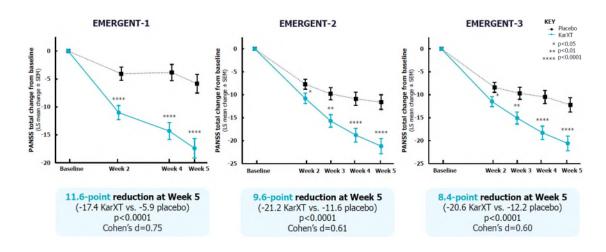


# KarXT in schizophrenia: Compelling efficacy and differentiated safety profile across three studies

#### COMPELLING EFFICACY

EMERGENT-1, 2 And 3 Trials of KarXT in Schizophrenia

Primary endpoint: Change in baseline PANSS total score vs. placebo at Week 5



#### DIFFERENTIATED SAFETY PROFILE

- KarXT is not associated with common side effects of approved treatments, including weight gain, increase in prolactin levels, extrapyramidal symptoms, akathisia and/or sedation
- Discontinuation due to TEAEs was similar between KarXT and placebo
- Most common TEAEs were mild to moderate, with most being cholinergic and resolving over time with repeated dosing

### Expansion opportunities supporting future growth

#### IN REGISTRATIONAL DEVELOPMENT BY KARUNA

### Adjunctive schizophrenia

- Need to improve on current SOC agents
- KarXT has complementary MoA with differentiated safety
- ARISE registrational trial underway
- Data expected 2025

### Alzheimer's disease psychosis

- No approved therapies
- Compelling data from Xanomeline alone
- Acts directly at muscarinic receptors unlike PAMs that require acetylcholine conditions
- M1 agonism alongside M4 activity in KarXT could uniquely improve cognition
- ADEPT registrational trials underway
- Data expected 2026

#### **FUTURE INDICATIONS**

### Alzheimer's disease agitation

 Xanomeline has demonstrated promising clinical data across symptomatology in Alzheimer's disease

#### Bipolar I disorder

 M1/M4 activation believed to modulate dopamine mediated manic behaviors while preserving cognition



# Indications currently in development comprise large patient populations and high unmet need

#### **SCHIZOPHRENIA**

~ 1.6M people<sup>1</sup>

in U.S. are treated for schizophrenia

~70% of patients

on current therapies are not well managed

#### **ALZHEIMER'S DISEASE PSYCHOSIS**

>6M people<sup>2</sup>

in the U.S. living with Alzheimer's disease

~40% of diagnosed patients

have psychosis

- Currently no approved treatments for ADP
- Same physician call point as Alzheimer's disease

High unmet need for new option that provides strong efficacy, clean safety and ability to add onto existing medicines

Potential first-in-disease treatment for ADP, an area with significant disease burden

### KarXT's benefit-risk profile is clearly differentiated

						REXULTI brexpiprazole [2mg] tablets	Vraylar (cariprazine) capsules	CAPLYTA (lumateperone) capsules	
	Risperidone <sup>1</sup>	Olanzapine <sup>2</sup>	Quetiapine IR <sup>3</sup>	Aripiprazole <sup>4</sup>	Lurasidone <sup>5</sup>	Brexpiprazole <sup>6</sup>	Cariprazine <sup>7</sup>	Lumateperone <sup>8</sup>	KarXT*
PANSS Placebo-subtracted difference	-6.0 <sup>9</sup>	-8.9 <sup>5,10</sup>	-7.8 <sup>11</sup>	-8.8	-8.2	-6.5	-8.3	-5.0	-9.9
Effect size <sup>12</sup>	0.6	0.6	0.4	0.4	0.3	0.313	0.414	0.315	0.65
Weight increase >7% of weight short-term trials	21%	22%	23%	8%	5%	11%	8%	<b>9</b> % <sup>16</sup>	5.3%
EPS	17%	32%	15%	13%	14%	5%	19%	<b>7</b> %	1.5%
Sedation/ somnolence*	10%	29%	18%	12%	17%	2%	8%	24%	4.7%
Nausea	9%	Not reported	Not reported	15%	10%	Not reported	7%	9%	17.1%
Vomiting	Not reported	4%	6%	11%	8%	Not reported	5%	3%	10.9%

All data come from the prescribing information except PANSS data for risperidone, olanzapine, and quetiapine IR as well as the weight for lumateperone, Pooled data for adverse events are shown when available; if unavailable, the highest incidence is reported. Data is used for reference and for illustrative purposes only; no head-to-head comparisons conducted.

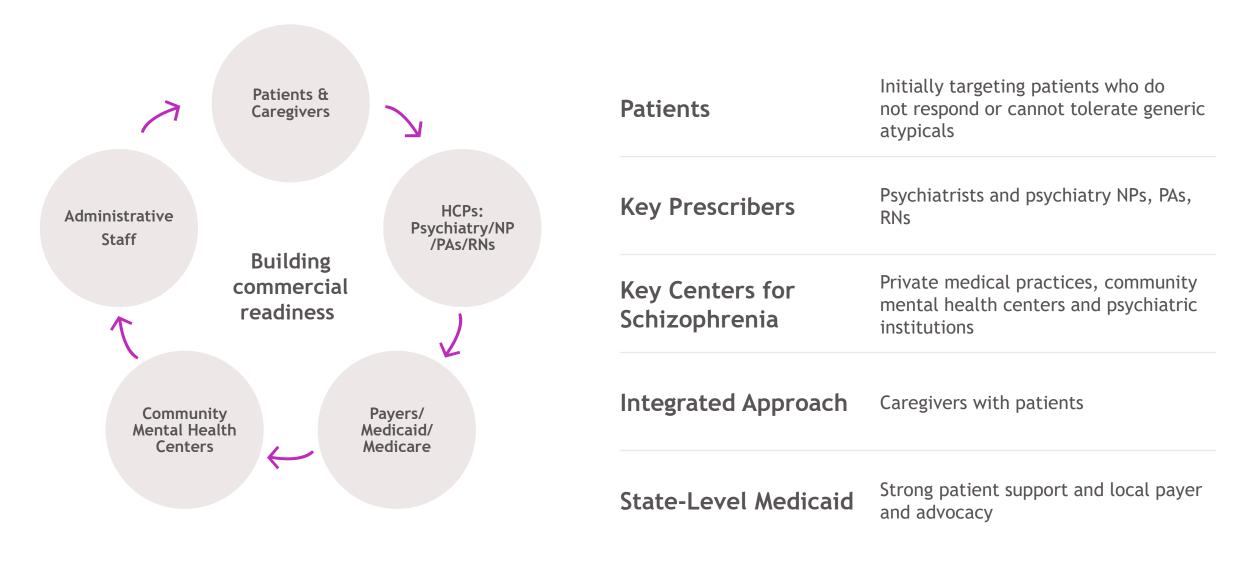
Source: 1. Risperdal. Prescribing information. Janssen Pharmaceuticals, Inc.; 2022. 2. Zyprexa. Prescribing information. Eli Lilly and Company; 2021. 3. Seroquel. Prescribing information. AstraZeneca; 2009. 4. Abilify. Prescribing information. Otsuka Pharmaceutical Co., Ltd.; 2022. 5. Latuda, Prescribing information, Sunovion Pharmaceuticals Inc.; 2022. 6. Rexulti, Prescribing information, Otsuka Pharmaceutical Co., Ltd.; 2021. 7. Vraylar, Prescribing information, Intra-Cellular Therapies, Inc.; 2022. 9. Lieberman JA, et al. Biol Psychiatry. 2016;79(12):952-961. 10. Lybalvi. Prescribing information. Alkermes, Inc.; 2021. 11. Seroquel XR. Prescribing information. AstraZeneca; 2022. 12. Leucht S, et al. Lancet. 2013;382(9896):951-962.13. Correll CU, et al. Schizophr Res. 2016;174(1-3):82-92. 14. Marder S, et al. Eur Neuropsychopharmacol. 2019;29(1):127-136. 15. Correll CU, et al. JAMA Psychiatry. 2020;77(4):349-358. 16. Kane JM, et al. International Clinical Psychopharmacology. 2021;36:244-250.

\*KarXT data is pooled from EMERGENT 1-3.



<sup>\*</sup>Sedation and somnolence data are shown as reported; if both were reported, they have been combined (aripiprazole and KarXT).

### We have a robust go-to-market strategy



# Significant opportunity for value creation for BMS, strengthening our presence in Neuroscience

#### Financial overview of the acquisition of Karuna Therapeutics

#### **Transaction Details**

- Purchase price: \$330.00/share in an all-cash transaction
- ~53% premium to closing share price as of Dec. 21, 2023
- Total consideration: ~\$14.0B implied transaction value, net of estimated cash of ~\$12.7B
- Will fund transaction primarily with new debt

#### **Deal Value**

- KarXT:
  - PDUFA Sept. 26, 2024
  - Multi-billion-dollar sales potential
  - Opportunity for series of indications supporting continued growth
- Additional value from pipeline of assets

#### Financial Impact\*

- Closing expected 1H 2024
- Expect ~\$0.30 non-GAAP dilution/share in 2024, primarily from financing costs
- Maintain operating margin above 37%
- 2024 Guidance to be provided on Q4 2023 Earnings Call

#### **Capital Allocation**

- No change to capital allocation priorities
- Retain capacity for additional business development
- Remain committed to the dividend
- Committed to maintaining strong investment grade rating

### **Q&A**



Chris Boerner, Ph.D.
Chief Executive Officer



Adam Lenkowsky
Executive Vice President,
Chief Commercialization Officer



**David Elkins**Executive Vice President,
Chief Financial Officer



Samit Hirawat, M.D. Executive Vice President, Chief Medical Officer, Global Drug Development



Robert Plenge, M.D., Ph.D. Executive Vice President, Chief Research Officer, Head of Research



Richard Hargreaves, Ph.D.
Senior Vice President, Neuroscience
Thematic Research Center

# Bristol Myers Squibb™