

# **Fourth Quarter 2018 Financial Results**

February 22, 2019

#### Introduction

Patty Eisenhaur, Vice President, Investor Relations and Communications

## **Corporate Update**

Craig Wheeler, President and Chief Executive Officer

#### Fourth Quarter 2018 Financial Results

Michelle Robertson, Chief Financial Officer

## Closing Remarks

Craig Wheeler, President and Chief Executive Officer

## **Forward-Looking Statements**

This presentation contains forward-looking statements about our financial outlook, business plans and objectives and other future events and developments. These forward-looking statements include, but are not limited to statements about our pipeline; the design, timing and goals of clinical trials and the availability, timing and announcement of data and results; the use, efficacy, potency, safety, tolerability, convenience and commercial potential of our product candidates, including their potential as best-in-class agents; the timing of regulatory submissions, potential regulatory approvals, development plans, market formation and launches of our product candidates and products; market potential and product revenues of our products and product candidates; our priorities, goals and strategy; our development timelines; potential future outlicensing/collaborations/partnerships; our cost reduction initiatives and spending projections; our future financial expectations and non-GAAP operating expense guidance and our anticipated collaborative reimbursement revenues and restructuring charges. Such forward-looking statements involve known and unknown risks, uncertainties, and other important factors, which could cause actual results to differ materially from those expressed or implied in such statements. These risks and uncertainties include, but are not limited to, unexpected regulatory decisions regarding any of these activities, unexpected expenses or inaccurate financial assumptions or forecasts; additional or increased litigation efforts by our competitors; insufficient resources or failure to prioritize competing projects and efforts; disputes with our collaboration partners; inability to successfully partner the development and commercialization of our product candidates; delays or unfavorable decisions of regulatory agencies; unfavorable regulatory guidance pronouncements; safety, efficacy or tolerability problems with our product candidates; unexpected negative results of clinical trials and competition for targeted indications or within targeted markets. Risks and uncertainties also include those referred to under "Risk Factors" in our Quarterly Report on Form 10-Q for the guarter ended September 30, 2018 filed with the Securities and Exchange Commission (SEC), as well as other documents that we may file from time to time with the SEC. Information provided in this presentation speaks only as of the date of this presentation, and we assume no obligation to update forward-looking statements to reflect events or circumstances occurring after this presentation.

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## **2018: A Transformative Year**

#### **2018: Transformed the Business**

#### **Completed Strategic Review**

Restructured to focus on novel drug development programs targeting rare immune-mediated disorders and late-stage biosimilars

#### **Novel Programs Progressed**

Expanded biology and clinical capabilities M281 and M254 made meaningful progress

#### **Completed Equity Financing**

Raised \$230M

Year End 2018 Cash Balance: \$449M

### **2019: Advancing the Business**

#### **Clarified Focus**

Programs aimed at improving the lives of patients with immune-mediated disorders

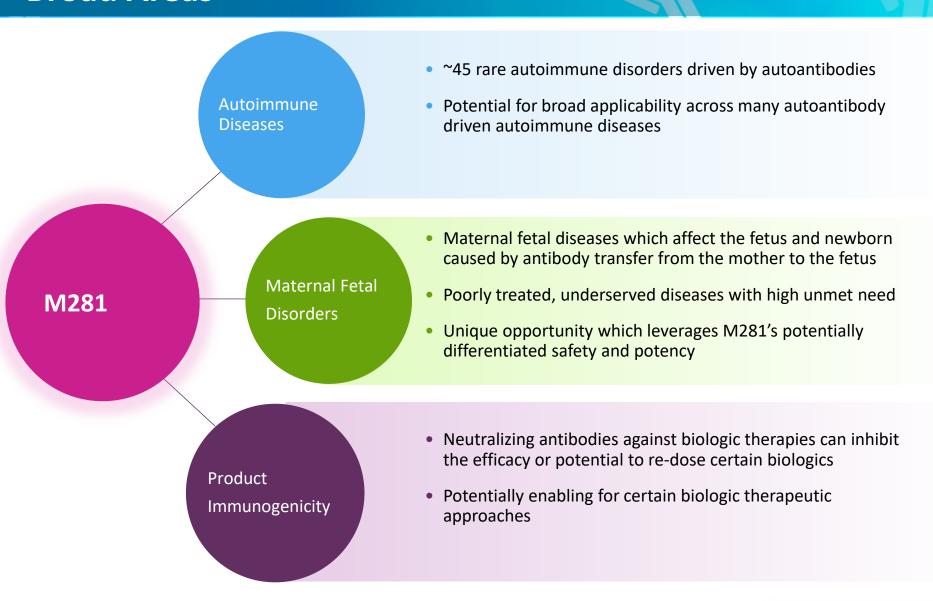
#### **Executing Clinical Trials**

3 product candidates in the clinic for the treatment of rare immune-mediated disorders and 2 late-stage biosimilar candidates

#### **Identifying New Product Candidates**

Sialylation and Fc multimerization platforms to identify new candidates which modulate the immune system

# M281 has Potential Commercial Opportunity in Three Broad Areas



## M281 Currently in Two Clinical Trials

## **Myasthenia Gravis (MG)**

- Neuromuscular Autoimmune Disease
  - Autoantibodies against acetylcholine receptors (AChR) or the muscle-specific receptor tyrosine kinase (MuSK)
- Effectively blocks the excitatory action of acetylcholine
- Bimodal age distribution: younger women and older men prototypical patients

65,000 patients in the US, 85% with Generalized Myasthenia Gravis (gMG)

# Hemolytic Disease of the Fetus and Newborn (HDFN)

- Mother's alloantibodies to fetal red blood cells pass through placenta and cause fetal anemia
  - Fetal complications include severe anemia, jaundice, congestive heart failure, hydrops, and fetal death
- Invasive intrauterine transfusions are the standard of care
  - Cause own morbidity (bleeding, infection risk)
- 20% fetal mortality in high risk population

4,000 – 8,000 HDFN cases per year in the United States

# Generalized Myasthenia Gravis (gMG) Phase 2 Clinical Trial Objectives and Design

#### **Primary Objectives**

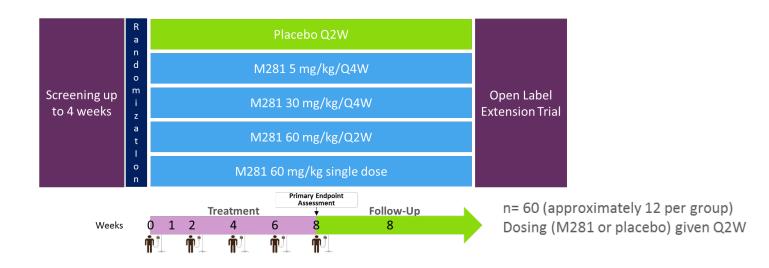
#### To evaluate:

- The safety and tolerability of treatment with M281
- The efficacy of M281 as measured by the change in MG – Activities of Daily Living score

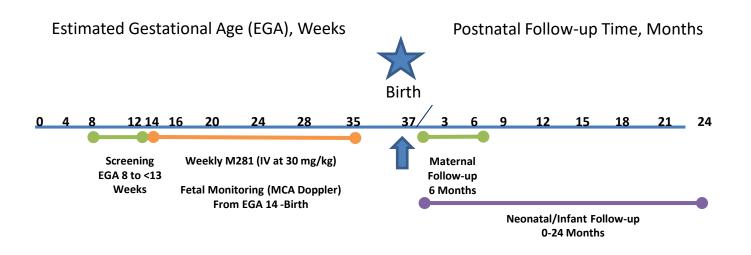
#### **Secondary Objectives**

#### To evaluate:

- The efficacy of M281 as measured by changes in the Quantitative MG score and the MG Quality of Life – 15 Scale
- The Pharmacokinetics (PK) of M281 injection
- The Pharmacodynamics (PD) activity of M281 as measured by total serum IgG



# M281: Phase 2 POC Clinical Trial Design in Early Onset HDFN



Dose selection: 30 mg/kg weekly is aimed to achieve both:

- 1. Full receptor occupancy, a surrogate for blockade of placental FcRn and IgG transfer
- 2. Reduction of IgG to -85% of baseline

N=15

# M254: Hypersialylated IVIg (hsIgG) Phase 1/2 Proof of Concept Clinical Trial Underway

## M254 offers the potential to provide enhanced:

## **Potency**

Up to 10x increase in potency could allow for greater immune modulation

### **Convenience**

Enables lower dose, faster administration and potentially subcutaneous administration that could reduce the burden to patients and health systems due to shorter infusion times

## Safety profile

Decreased dose, reduced treatment-associated AE's

Clinical trial designed for rapid proof-of-concept

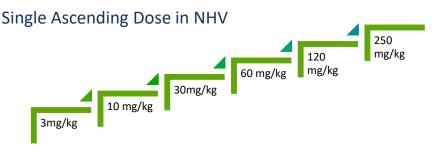


**Target Opportunities** 

80+ rare autoimmune disorders

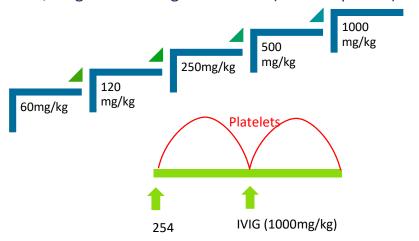
# M254: First-in-Human Phase 1/2 Clinical Trial Design in Immune Thrombocytopenic Purpura (ITP)

#### **PART A**



#### **PART B**

Open Label, Single Ascending Dose in ITP (fixed sequence)



#### **PART C**

Randomized, Cross-Over in ITP





#### **PART D**

Multiple Dose in ITP

M254 Dose TBD

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# Fourth Quarter 2018 Financial Results

	Q4 2018	Q3 2018
GAAP Net Loss <sup>(1)</sup>	\$8.2M	\$50.3M
	Q4 2018	Q3 2018
Product Revenue(2)	\$10.8M	\$13.6M
Research & Development Revenue(3)	\$32.1M	\$1.3M
Total Revenues	\$42.8M	\$14.9M
R&D Expenses	\$28.7M	\$30.7M
G&A Expenses	\$21.5M	\$20.4M
Restructuring	\$2.3M	\$15.5M
Total Operating Expenses(4)	\$52.5M	\$66.7M

<sup>(1)</sup> Net loss for Q3 and Q4 2018 includes restructuring charges of \$15.5 million and \$2.3 million, respectively. Q4 2018 also includes \$31.5 million revenue recognized related to Mylan's upfront payment, see (3) below.

<sup>(2)</sup> Decrease of \$2.8 million in Glatopa® revenues was due by lower net sales driven by competition.

<sup>(3)</sup> Q4 2018 includes \$31.5 million revenue recognized related to Mylan's upfront payment, increase of \$30.9 million versus Q3 2018 related to the partial termination of the Mylan collaboration agreement.

<sup>(4)</sup> Total GAAP operating expenses for Q3 and Q4 2018 includes restructuring charges of \$15.5 million and \$2.3 million, respectively.

# Fourth Quarter 2018 Non-GAAP Operating Expense & Cash Position

	3 Mos Ended December 31, 2018 (Actual)
Non-GAAP Operating Expense <sup>(1)</sup>	\$47.2M

(1) Non-GAAP operating expense is total operating expenses, less stock-based compensation expense, restructuring costs and collaborative reimbursement revenues. While Momenta believes this non-GAAP financial measure is useful to investors because it provides greater transparency regarding Momenta's operating performance, it should not be considered a substitute or an alternative to GAAP total operating expense. For the three months ended December 31, 2018 stock-based compensation was \$2.5 million, restructuring costs were \$2.3 million and reimbursement revenues from collaboration partners was \$0.5 million.

	Q4 2018	Q3 2018
Cash, Cash Equivalents and Marketable Securities	\$449.4M	\$281.6M

# Fourth Quarter & Full Year 2018 Financial Guidance

	2019 Quarterly Guidance <sup>(2)</sup>
Non-GAAP Operating Expense <sup>(1)</sup>	~\$45M - \$55M

- (1) Non-GAAP operating expense is total operating expenses, less stock-based compensation expense, restructuring costs and collaborative reimbursement revenues. While Momenta believes this non-GAAP financial measure is useful to investors because it provides greater transparency regarding Momenta's operating performance, it should not be considered a substitute or an alternative to GAAP total operating expense.
- (2) The Company has not provided a GAAP reconciliation for its forward-looking non-GAAP annual or quarterly operating expense because Momenta cannot reliably predict without unreasonable efforts the timing or amount of the factors that substantially contribute to the projection of stock compensation expense, which is excluded from the forward-looking non-GAAP financial measure. We do not anticipate significant restructuring costs in future periods. The Company expects collaborative reimbursement revenues to be approximately \$0 \$2 million per quarter in 2019.

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# 2019: A Year Focused on Operational Execution

Portfolio	Program	Goal/Milestone
Novel Drugs	M281 (anti-FcRn) M254 (hslgG) M230 (rFc multimer) Research	Enroll MG and HDFN studies; initiate third indication Advance Phase 1/2 proof of concept study in ITP Phase 1 completion in 2019 (by partner CSL) Advance internal research & collaborations
Biosimilars	M923 (b-HUMIRA® candidate) $M710$ (b-EYLEA® candidate)	Identify collaboration partner Advance Phase 3 towards completion

2018 Year End Cash Balance: \$449 million

2019 Quarterly Net Operating Expense: \$45-55 million

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