

# MOMENTA



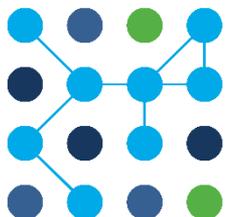
## Momenta Pharmaceuticals, Inc.

*November 2017*



# 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 use, efficacy, and commercial potential of our products and product candidates; the timing of clinical trials and the availability and timing of reporting results; the timing of regulatory submissions, regulatory approvals and launches of our product candidates, including Glatopa<sup>®</sup> 40 mg (glatiramer acetate); statements regarding work being done to bring Glatopa 40 mg to market; our priorities, goals and strategy; potential future out-licensing/collaborations/partnerships; and our development timelines. 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 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; delays or unfavorable decisions of regulatory agencies; unfavorable regulatory guidance pronouncements; safety, efficacy or tolerability problems with our product candidates; 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 quarter ended September 30, 2017 that we 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.



## Analytic Data-Driven Approach

- Proven expertise in high-resolution analytics, biological characterization and process engineering
  - First to achieve FDA approval of complex generic versions of LOVENOX® and COPAXONE® 20mg
- Provides advantage in biosimilar and novel drug development



## Diverse & Growing Pipeline

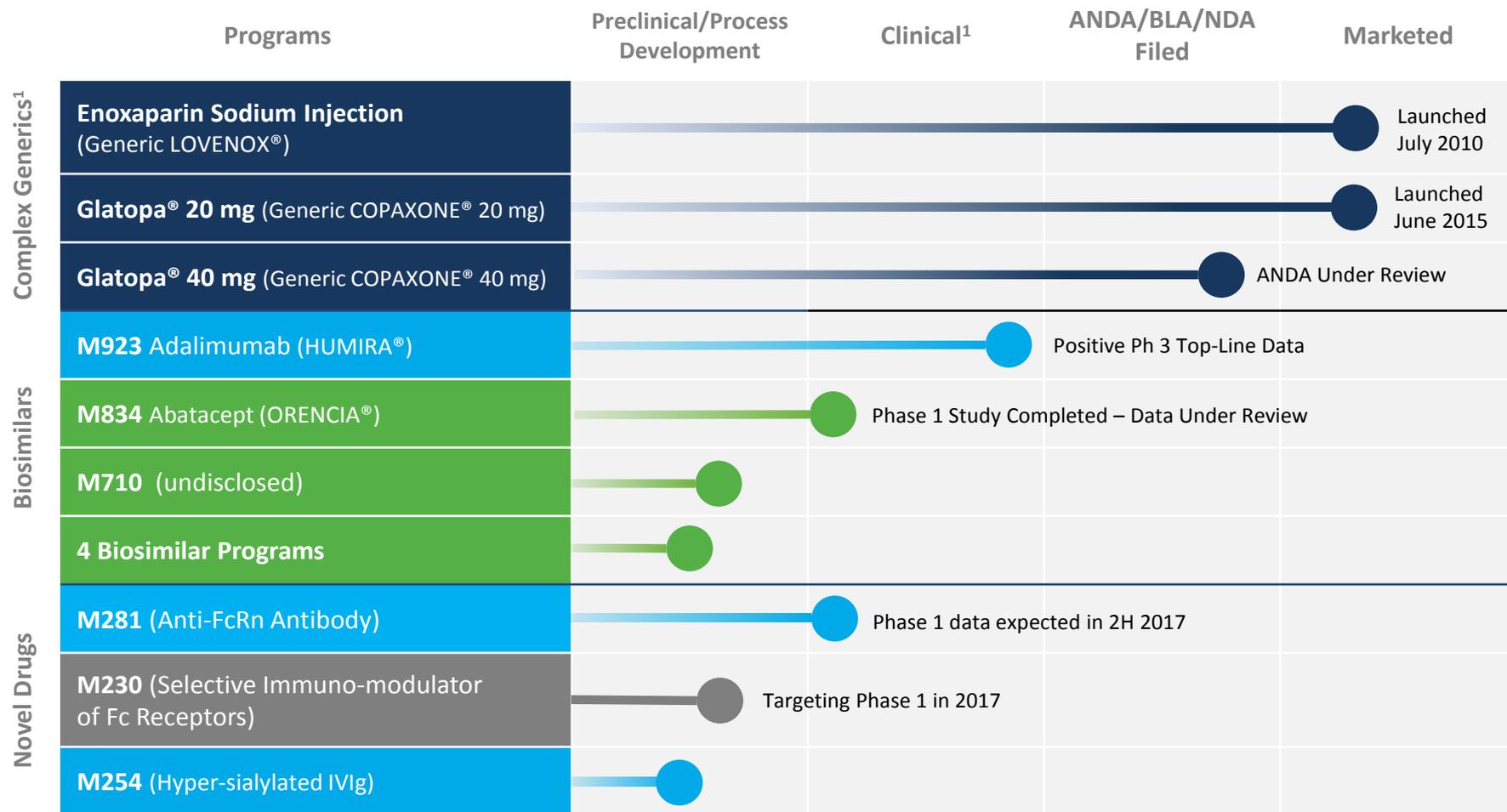
- Manages risk
- Maximizes upside potential
- Well funded with capital allocation flexibility



## Collaborations with Industry Leaders

- Building our business through strong collaborations
  - CSL, Mylan, Sandoz

# Momenta's Technology Platform has Generated a Robust Pipeline of Commercial Products & Product Candidates



Momenta & Sandoz

Momenta

Momenta & Mylan

Momenta & CSL

<sup>1</sup>Clinical safety/efficacy trials have not been required for these complex generic drug applications



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# Complex Generics

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Biosimilars

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Novel Drugs for Autoimmune  
Indications

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# Potential for Glatopa® 40 mg Approval and Launch in Late 2017 or Early 2018

- February 16, 2017 - Pfizer, Sandoz's contracted fill/finish manufacturer of Glatopa, notified us they had received a warning letter related to its McPherson, Kansas manufacturing facility
- No outstanding questions from the FDA regarding Sandoz's Glatopa 40 mg ANDA
- Pfizer has submitted a comprehensive response to FDA warning letter
  - Response indicates that the majority of the commitments Pfizer made to the FDA following the May-June 2016 inspection have been completed
  - Pfizer is implementing a comprehensive quality improvement plan to address outstanding observations
- Momenta is working closely with Sandoz to be able to bring Glatopa 40 mg to the market as soon as possible
  - Identified potential second fill/finish manufacturer

# Glatopa<sup>®</sup>: First FDA-Approved, Substitutable Generic Daily COPAXONE<sup>®</sup> 20 mg for Multiple Sclerosis

- Momenta Q3 2017 profit share of \$11M compared to \$23M in Q3 2016
- In the third quarter of 2017, Momenta earned a \$10M milestone payment from Sandoz for Glatopa 20 mg achieving a second year in the U.S. as the sole FDA-approved generic COPAXONE at that time and achieving a certain level of contractually defined profits in the U.S.
- Glatopa 20 mg prescriptions represented approximately 40% of the 20 mg glatiramer acetate market in the U.S.<sup>1</sup> at the end of Q3 2017, prior to Mylan's entry into the COPAXONE market
- Sandoz has an established patient support services hub and relationships with wholesalers, retailers, payors, PBM's and plans

<sup>1</sup> Source: Symphony Health Solutions prescription data plus Sandoz internal estimates to include key Glatopa 20 mg accounts not reported in Symphony.



Complex Generics

**Biosimilars**

Novel Drugs for Autoimmune  
Indications

# Our Approach to Biosimilars

1

## Build a broad and diverse portfolio

**Portfolio of complex biologics including mAbs and fusion proteins**

Capture scale, technology and regulatory synergies

Smooth revenue flow

2

## Gain competitive advantage through our scientific approach and regulatory strategies

**Biocharacterization platform, analytic toolset and process control offer potential added-value opportunities:**

Extrapolation of indications, reduced trial scope and interchangeability designation

Process and scale-up precision to engineer in quality and improve P.O.S.

Integrated regulatory and legal strategy to launch at market formation

3

## Ensure products are positioned to capture the global opportunity through collaborations

**Identify and collaborate with strategic partners with:**

Global commercial capabilities

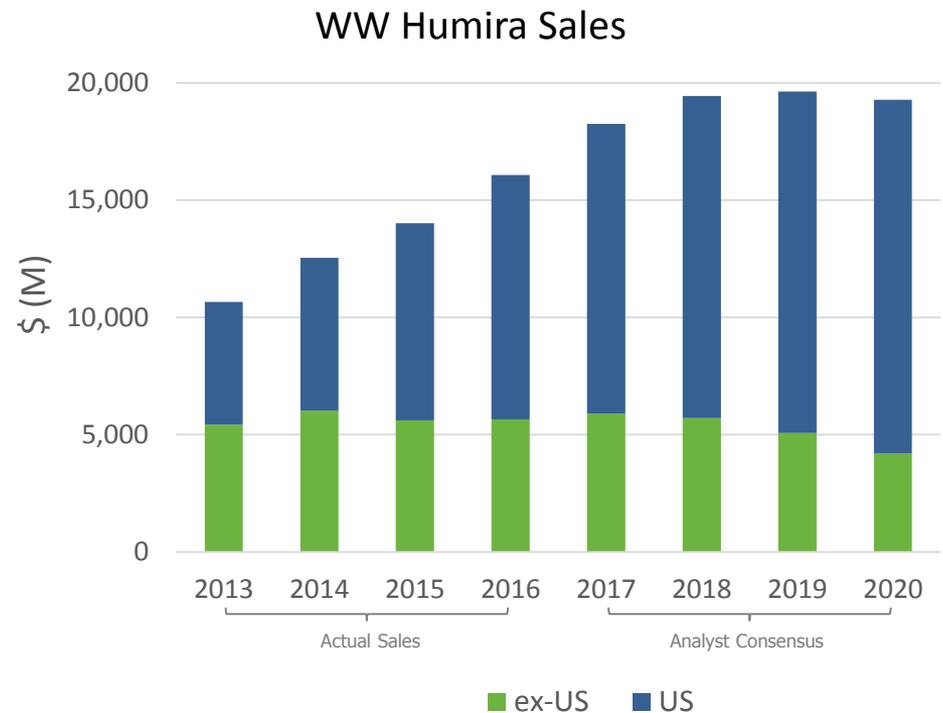
Low cost manufacturing strategies



# M923, Biosimilar HUMIRA® (adalimumab) Candidate

## Fully-owned asset with positive Phase 3 clinical trial results

- Working toward first submission for marketing approval in Q4 2017
- Expect first U.S. market formation in the 2022-2023 timeframe, subject to marketing approval, patent considerations and litigation timelines
- Potential to re-partner M923 for enhanced deal economics



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Complex Generics

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Biosimilars

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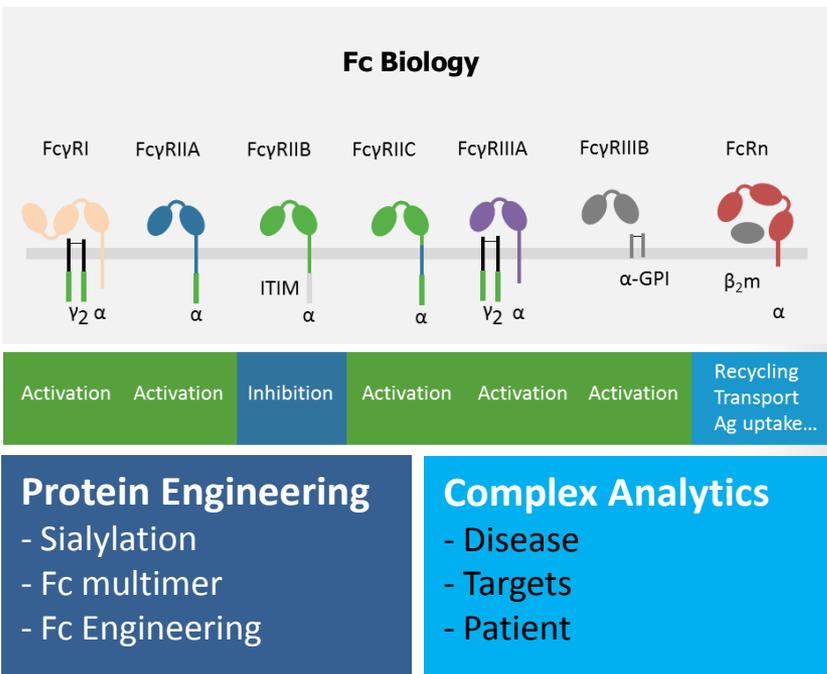
**Novel Drugs for Autoimmune  
Indications**

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# Our Fc Biology Platform Yields Multiple Candidates Targeting a Broad Set of Autoimmune (AI) Indications

## Platform



## Portfolio

M230 (SIF3)  
M281 (Anti-FcRn)  
M254 (hs-IVIg)

Next-Generation  
Molecules

## Opportunity

### Rare AI Diseases

Over 70 distinct disease indications

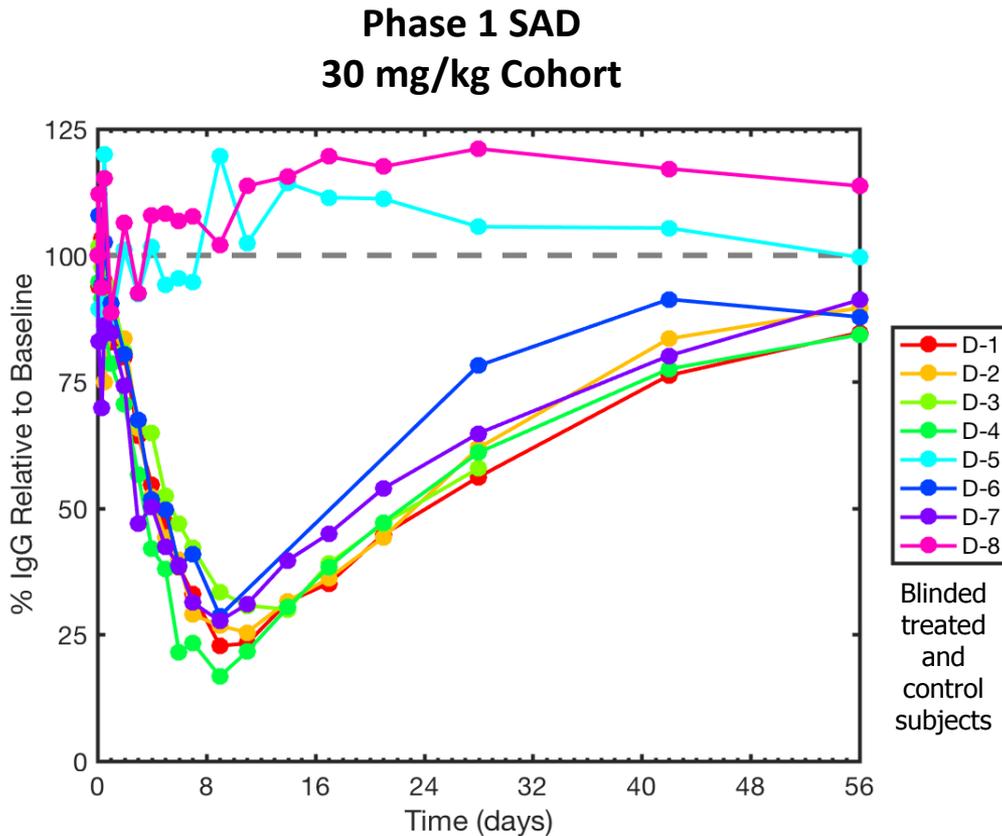
### Prevalent AI Diseases

RA, Psoriasis, Psoriatic arthritis, Crohn's, Ulcerative colitis, Ankylosing spondylitis

### Other Fc-mediated Diseases

Immuno-oncology, Immunology, Oncology

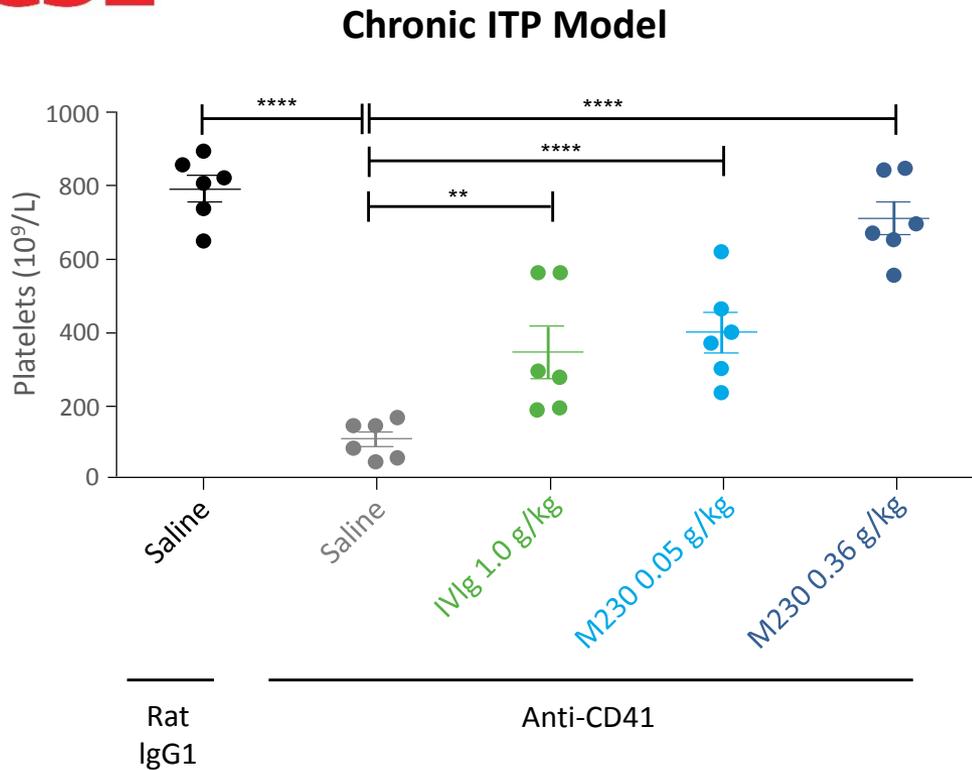
# M281: Fully Human Monoclonal Antibody (mAb) Targeting the Neonatal Fc Receptor (FcRn)



A single dose of 30 mg/kg achieved up to 80% reduction of circulating IgG

- M281 rapidly reduces circulating IgG antibodies in non-human preclinical and first in human studies
- Potential to use acutely or intermittently for autoantibody clearance across a range of IgG-driven autoimmune diseases
- Phase 1 single ascending dose (SAD) study in healthy volunteers completed
- Phase 1 multiple ascending dose (MAD) study completed; plan to report top-line data in Q4 2017

# M230, Selective Immunomodulator of Fc Receptors (SIF3), in Collaboration with CSL



Source: Ortiz et al. *Science Translational Medicine*, 16 November 2016, Volume 365, pp 1-13

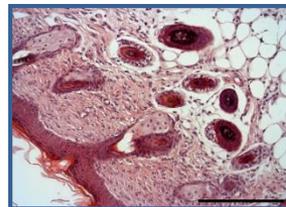
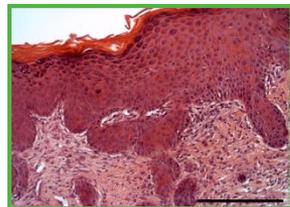
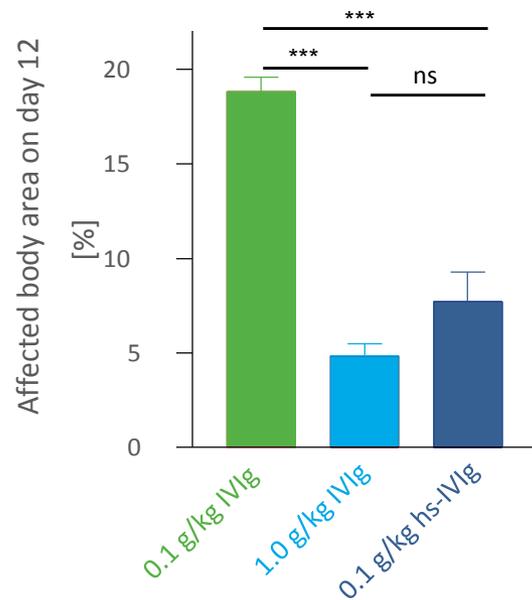
- Homogenous recombinant Fc-derived drug candidate designed with enhanced avidity and affinity for Fc receptors
- M230 shows higher potency and efficacy at a lower dose than IVIg in preclinical chronic ITP model
- Engineered a high-producing GMP-manufacturing cell line and completed GLP toxicology
- Development plan in place; CSL is targeting a clinical trial in Q4 2017, subject to regulatory feedback

# CSL Agreement and Collaboration Opt In

- In September 2017, Momenta announced it had opted in to a 50% cost and U.S. profit share agreement with CSL for the development and commercialization of all products developed under the CSL agreement, including M230
- 50% cost/profit share arrangement terms include:
  - Momenta will fund 50% of global R&D costs and 50% of U.S. commercialization and manufacturing costs in exchange for a 50% share of U.S. profits
  - Eligible for approximately \$300M in milestone payments
  - Eligible for royalties for territories outside the U.S.
  - Option to co-promote in the U.S.
  - Right to opt-out of cost/profit share with reversion to pre-arranged milestone payments and royalties

# M254 (hsIVIg), Shows up to 10x Enhanced Anti-Inflammatory Activity in Preclinical Autoimmune Models

## Skin Blistering Pemphigoid Model



\*\*\*=p <0.001, ns= no significance

Source: Washburn et al. *PNAS* 2015 112 (11) E1297-E1306

- Sialylation of the Fc region of IgG mediates the anti-inflammatory effects of IVIg
- Momenta has developed a process to maximize sialylation to the Fc and maximize therapeutic effects
- M254 has the potential to be a more potent, subcutaneous alternative to IVIg
- Plan to initiate an IND-enabling toxicology study in 2017 and to initiate a clinical trial in 2018

# Well Funded with Capital Allocation Flexibility

1

## Cash Position

\$423M at the quarter ended  
September 30, 2017

2

## Cash Inflows

Glatopa® 20 mg revenues from Sandoz  
profit share

Potential future Glatopa 40 mg revenues  
from Sandoz profit share

Current collaborations include potential  
future development and commercial  
milestone payments

Potential future out-  
licensing/collaborations (M923, novel  
programs)

3

## Disciplined Cash Burn

Stage-gate approach to new  
development programs

Ability to opt-out of co-fund  
arrangement with CSL and reduce  
spend on programs through  
outlicensing

# Momenta's Near-and Long-Term Goals

## BIOSIMILARS

## COMPLEX GENERICS

## NOVEL DRUGS

**2017**

- M923, biosimilar HUMIRA® candidate, working toward submission for marketing approval in Q4 2017

- Potential FDA approval of ANDA for Glatopa® 40 mg, generic COPAXONE® 40 mg
- Potential for Sandoz launch of Glatopa 40 mg

- Complete M281, anti-FcRn antibody, Ph 1 clinical trial and report data
- CSL to initiate M230, SIF3, Ph 1 clinical trial
- Initiate IND enabling toxicology study for M254

**2020+**

- M923, biosimilar HUMIRA® candidate, on the market
- Launch 1-2 biosimilar product candidates per year

- Glatopa 40 mg, generic COPAXONE® 40 mg, on the market

- Launch 1-2 novel drugs for autoimmune indications

**MOMENTA**



**Momenta Pharmaceuticals, Inc.**

