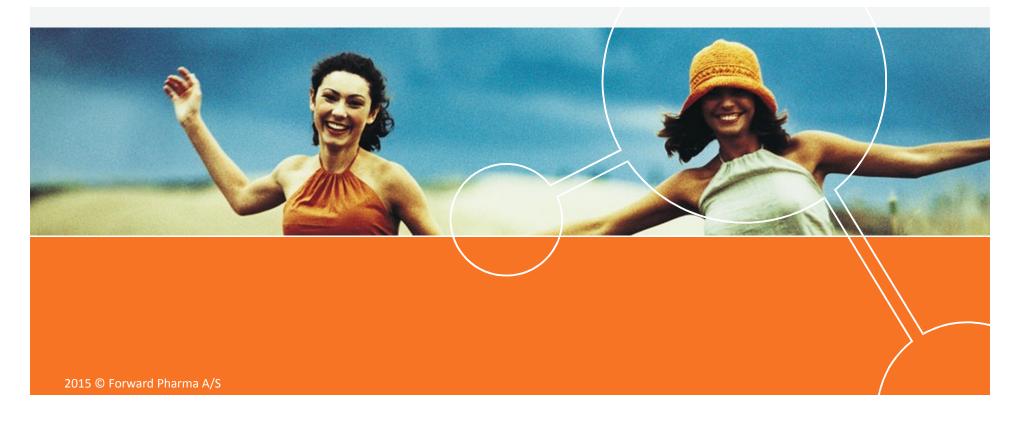


# **FP187: DMF for Multiple Sclerosis**

Jefferies Autumn Global Healthcare Conference

November 18, 2015



# **Forward-Looking Statements**



This presentation contains forward-looking statements about Forward Pharma A/S based on management's current expectations which are subject to known and unknown uncertainties and risks. Our actual results could differ materially from those discussed due to a number of factors, including, but not limited to, our ability to raise additional financing on favorable terms, the success of our clinical trials, our ability to obtain regulatory approval of FP187, our success in maintaining and defending our patent estate and other risk factors included in our filings with the U.S. Securities and Exchange Commission. We are providing this information as of the date of this presentation and do not undertake any obligation to update any forward-looking statements contained in this presentation as a result of new information, future events or otherwise.

# **FWP – The Investment Opportunity**





### **Introduction to Forward Pharma**



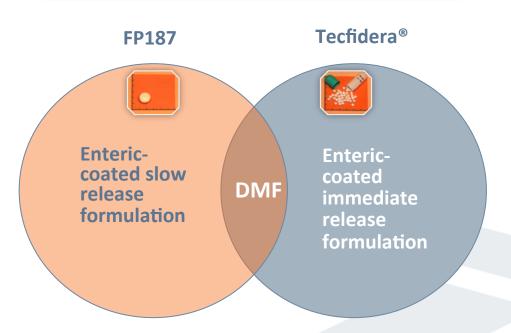
- Focused on DMF since 2004
- FP187: Proprietary slow release formulation of DMF
- 480 mg daily dose in MS patent application allowable and '871 patent interference declared
- RR-MS Phase 3 trial: 1 trial, 1 year submission endpoint
- IPO priced 10/14/2014, raised \$235 M in gross proceeds
- Well capitalized to pursue patent and development strategies

### **FP187 Clinical Differentiation**



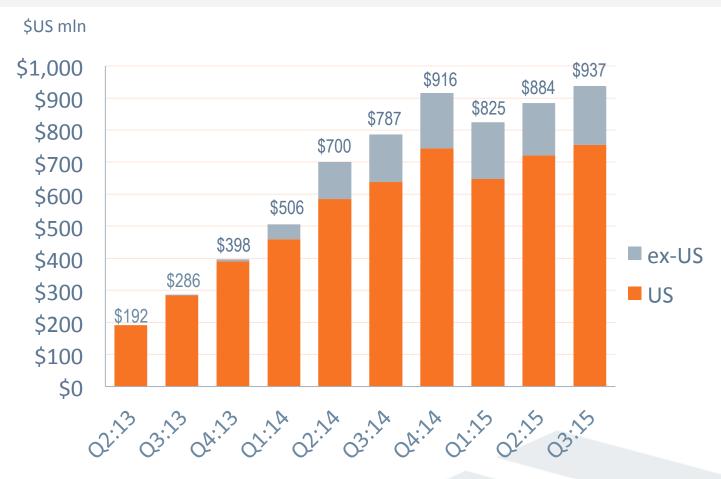
- Same active pharmaceutical ingredient as Tecfidera®
- FP187 utilizes an "erosion matrix" formulation

### **Formulation Differentiation**



## Tecfidera® RR-MS Global Sales





\* 480 mg/day is the only approved dose for RR-MS

Source: Biogen Inc.

# **USPTO and EPO Claims Covering 480 mg/day**



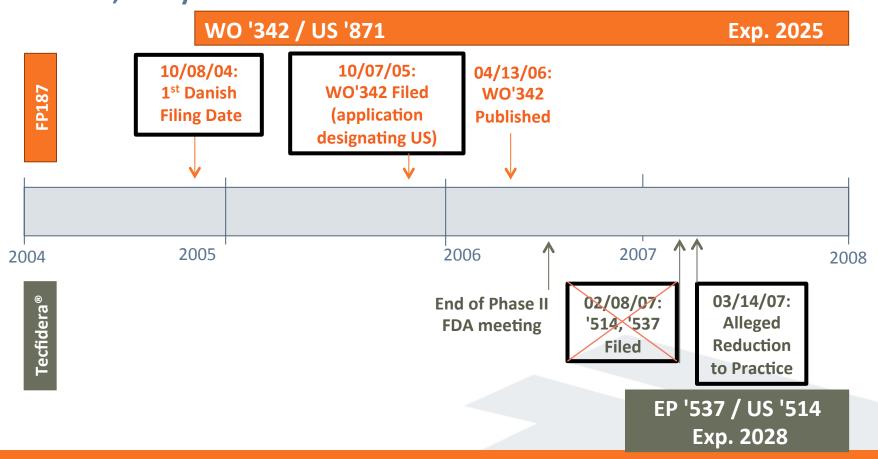
# 6 separate patent applications with claims to 480 mg/day with the same priority date of at least as early as October 7, 2005

	Application Number	Description
	11/576,871	Treating MS with DMF at 480 mg/day * Interference declared; FWP as Senior Party – 4/13/15
SN	14/213,399	Up-titration of DMF to 480 mg/day doses for the treatment of MS Final rejection issued subject to further action by us
	14/212,503	Treating MS with DMF at 480 mg/day to reach certain MMF levels in the bloodstream Final rejection issued subject to further action by us
European	EP14172398.1	Treating MS with 480 mg/day of DMF wherein the pH controlled release compositions have an enteric coat  * Issued – 5/20/15; Patent #EP2801355
	EP14172396.5	Treating MS with 480 mg/day of controlled release DMF Negative search report issued by EPO
	EP14172390.8	Treating MS with 480 mg/day of controlled release DMF with particular in vitro dissolution profile  Positive search report issued by EPO

# Forward Pharma Detailed Timeline: 2004-2008



# FP187 core composition patent applications filed at least 1 year, 4 months, 1 day earlier



# **USPTO Interference Proceeding**



## Interference declared April 13, 2015

A patent interference is an administrative proceeding at the USPTO used to determine which party is the first to invent a common invention claimed by both parties

# Forward has "Senior Party" status

The Senior Party has the earliest effective filing date to the common invention; entitled to the presumption that it is the first inventor

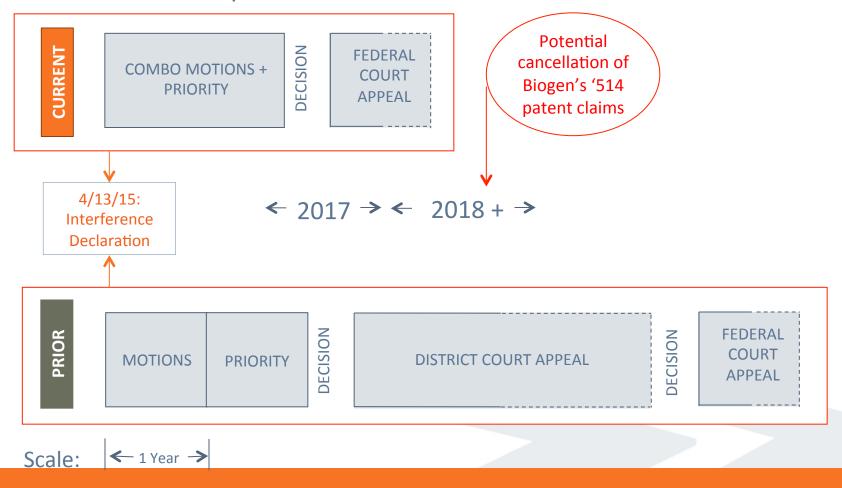
# Interference ongoing

- Interference "redeclared" on August 19, 2015, confirming Forward as Senior Party
- Biogen not entitled to benefit of priority to its February 8, 2007 US provisional application but has been granted permission to file a motion to claim that priority.

# **Updated Interference Process**



- Compressed timeline: combined phases, no district court appeal route
- Final decision expected in 2018



# **Senior vs. Junior Party**



# Forward Pharma: "Senior Party"

Has the earliest effective filing date to the invention; entitled to presumption that it invented first

# Biogen: "Junior Party"

Has the burden of proof to show a date of invention that predates our invention

# 480 mg/day for MS: Forward Pharma '871 and Biogen '514



### Forward Pharma US '871

 A method of treating...multiple sclerosis comprising orally administering ...(a) a therapeutically effective amount of dimethyl fumarate...wherein the therapeutically effective amount...is 480 mg per day



Filing date: 10/08/04

## Biogen Idec US '514

- A method of treating...multiple sclerosis comprising orally administering...a therapeutically effective amount of dimethyl fumarate...about 480 mg per day
- Earliest filing date: 02/08/07

# **Summary Timeline for the Interference**



- December 11, 2015: File Biogen Motion 4 (priority)
- March 3, 2016: File Forward Motion 19 (priority)
- June 1, 2016: File oppositions to all motions
- August 8, 2016: File all replies
- January 9, 2017: Default oral argument

# **Provisional Rights**



# Potential royalty initiation date

- Forward's '871 claims published on April 10, 2014
- Biogen was provided a copy of Forward's published claims on September 8, 2014

# **Reasonable Royalty**



- Patentee who wins infringement case is entitled to no less than a "reasonable royalty"
- Legal framework:
  - Hypothetical negotiation between willing licensor and willing licensee on the eve of infringement
    - What is the maximum the infringer would pay the patentee to be able to stay on the market
    - What is the minimum the patentee would accept to allow accused product to stay on the market
- Analysis assumes: patent is valid and infringed

# **Royalty Regimes**



	Academic Inventor	Industrial Inventor
Competitive Product	NO	YES
Active R&D Spend	NO	YES
Ability to Commercialize	NO	YES
Opportunity Cost	LOW	HIGH
Royalty	LOW	HIGH
Example	Cabilly	Late-stage Biotech Deals

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## Potential FP187 Patent Protection in the US



FP187

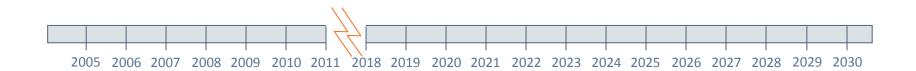
**EROSION MATRIX (US '420)** 

2030

**CORE COMPOSITION** 

"480 MG"

2025



**Tecfidera**®

# **Potential FP187 Patent Protection in Europe**





**Tecfidera**®

EP '537 "480 MG" 2028

\* EP '063 is in opposition proceedings at the EPO

# **USPTO and EPO Claims Covering 480 mg/day**



# 6 separate patent applications with claims to 480 mg/day with the same priority date of at least as early as October 7, 2005

	Application Number	Description
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# **German Utility Model and '355 Patent Infringement**



- Forward Pharma filed a lawsuit against Biogen on November 18, 2014 on the Utility Model
- Alleges infringement by Biogen's marketing of Tecfidera® in Germany with a label instructing a daily dose of 480 mg for MS
- The granted '355 patent is infringed by Biogen's marketing of Tecfidera® at the 480 mg dose
- Infringement lawsuit added to the Utility Model lawsuit at the Regional Court in Dusseldorf. Separate oral proceedings on March 24, 2016

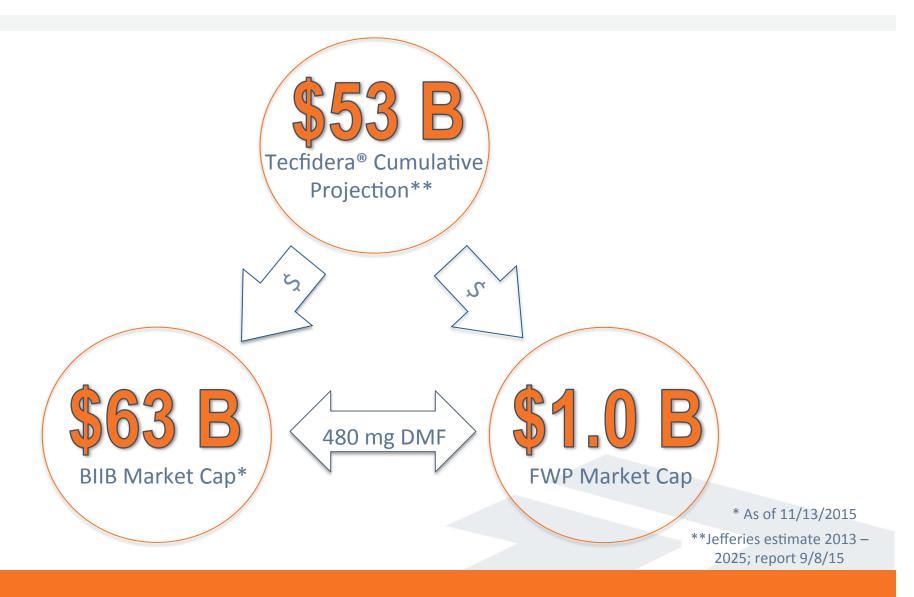
# **Support for our IP**



- US: USPTO has twice found allowable 480 mg/day to treat MS allowable as an invention; PTAB declared interference with Forward Pharma as Senior Party
- Europe: '8.1 EU patent application issued as patent EP2801355
- Competitors: References to our 480 mg/day patent application as prior art in opposition proceedings against Biogen in Europe from 9 opponents

## **BIIB to FWP Current Relative Valuation**





# **FP187 Clinical Strategy**



# 314 patients and healthy volunteers to date in FP187 clinical trials Clinical Trials to Date

#### FP187-101, 102, 103

- 3 Phase 1 clinical trials of 62 healthy male volunteers
- Studied:
  - PK properties of MMF
  - Comparative bioavailability vs.
     Fumaderm®
  - Safety and tolerability



#### Results

- Few and low peaks of MMF
- Similar bioavailability Profile indicating controlled and sustained release

#### FP187-201

- Phase 2 clinical trial of 252 psoriasis patients
- Studied
  - Efficacy using PASI75 as the primary endpoint
  - Safety and tolerability



#### Results

- PASI75 in 500 mg group (PP) (45.5%)
   vs. placebo (13.5%) p<0.01</li>
- Low flushing rates (17% for 500 mg and 13% for 750 mg FP187 arms)
- 100% of flushing events were mild or moderate

\* No patients with MS treated to date with FP187

# **FP187 Clinical Strategy**



## **Current status of ongoing development**





#### **API production**

- API production continues
- Up-scaling to large batches
- Technology transfer to secondary supplier





#### **Tablet production**

- Secondary supplier of tablets identified
- Validation of increased batch size ongoing

#### **Pre-clinical status**

Currently conducting additional preclinical studies on:

- Reproductive toxicity
- Chronic toxicity
- Long-term carcinogenicity

#### **Clinical trial status**

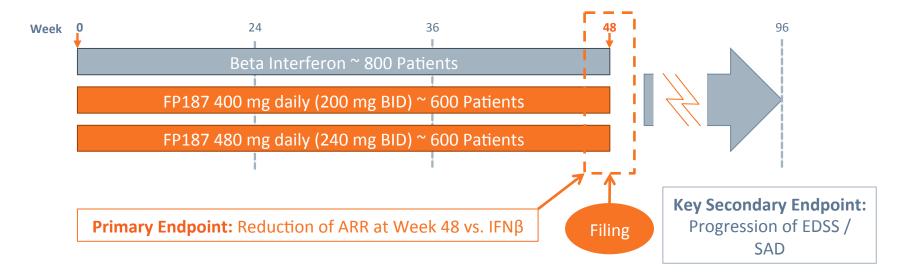
- Phase I studies planned and ongoing
- Phase III MS in prep with CRO, sites being identified
- Sourcing of comparator and placebo

# Planned Phase 3 Trial in RR-MS (FDA Meeting August 2013): FP187-MS-301



## **Trial Design**

Double-blind, double-dummy 48 week active comparator with two FP187 dosage groups



- One Phase 3 trial, 48 weeks in alignment with FDA pre-IND meeting in August 2013
- IND for MS filed on April 30, 2014; FDA "may proceed" letter sent on June 10, 2014

## **Financial Position**



# Well capitalized following IPO with an efficient business model

Balance Sheet (\$)		6/30/15 *
	<b>Cash and Investments</b>	\$202.5 M

Income Statement (\$ in thousands)	Quarter Ended June 30, 2015
R&D Expenses	\$9,999
G&A Expenses	\$3,547
Operating Loss	\$13,546

\* Unaudited

## **Management Overview**



### **Management**

- Peder M. Andersen, MD Chief Executive Officer & Chief Operating Officer
  - More than 25 years experience in the pharmaceutical industry
  - Several years experience in business development experience, both generic and proprietary in Europe
- Andrzej Stano
   Executive Vice President, Pharmaceutical
   Development and Production
  - More than 30 years in the pharmaceutical industry, most recently at GlaxoSmithKline
  - Development and production of a wide range of products
  - Extensive expertise in solid oral dose and modified release technologies

#### Joel Sendek Chief Financial Officer

- 18 years as a sell-side analyst, most recently as Managing Director, Healthcare Equity Research, Stifel Financial Corp.
- Former Head of Business Development, Progenics
- Corporate Finance, Goldman Sachs

#### Tom Carbone

#### Vice President, Finance and Controller

- Over 30 years of experience providing auditing and accounting services to public and private companies, many within the biotechnology industry
- Extensive experience with the reporting requirements for publicly listed companies
- Involved in numerous public and private financings including initial public offerings

## **Corporate Overview**



#### **Board of Directors**

- Florian Schönharting NB Capital
- J. Kevin Buchi
   Tetralogic, previously Teva,
   Cephalon
- Torsten Goesch, MD, PhD Rosetta Capital
- Jan G. J. van de Winkel, PhD Genmab
- Grant Hellier Lawrence Nunc A/S
- Jakob Mosegaard Larsen Nielsen Norager LLP

### **Scientific Advisors**

- Fred Lublin, MD

  Mount Sinai Hospital
- Giancarlo Comi, MD
   Hospital San Raffaela,
   Milan
- Kristian Reich, MD
   Dermatologikum Hamburg

# Jerry Wolinsky, MD

University of Texas, Medical School

- Per Soelberg Sørensen, MD Rigshospitalet, Copenhagen University Hospital
- Ulrich Mrowietz, MD Psoriasis-Center Kiel

### **Select Investors**

- Nordic Biotech
- BioScience Managers Limited
- The Baupost Group
- BVF Partners LP

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# **Key Upcoming Events**



- Interference proceeding progress at the USPTO
- US: Progress on 480 mg/day MS patent applications
- **EU:** Progress on 480 mg/day MS patent applications
- MS clinical development progress
- Psoriasis clinical development progress