

## FP187: DMF in Multiple Sclerosis

Bank of America Merrill Lynch Health Care Conference

May 14, 2015

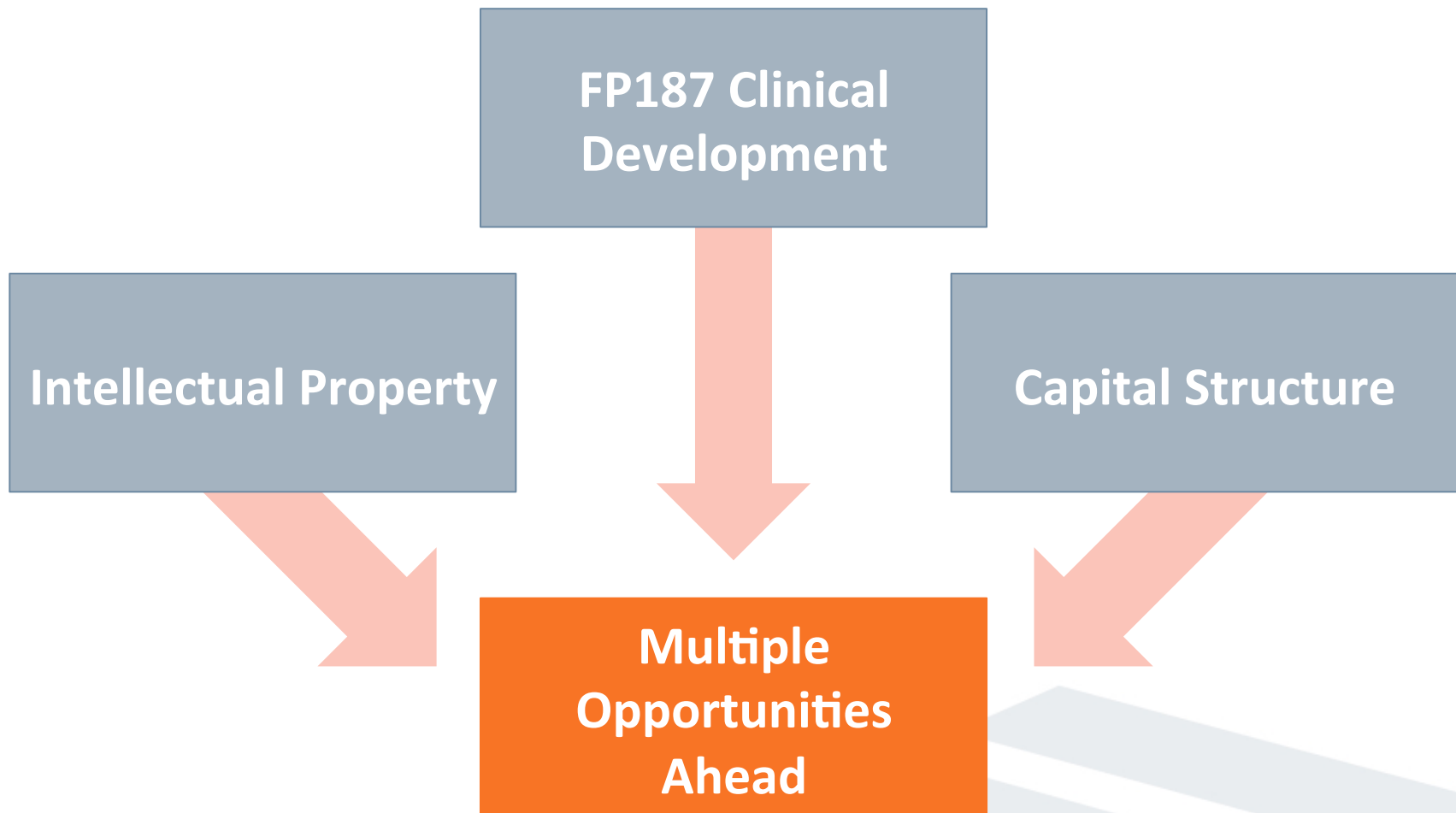


# Forward-Looking Statements



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

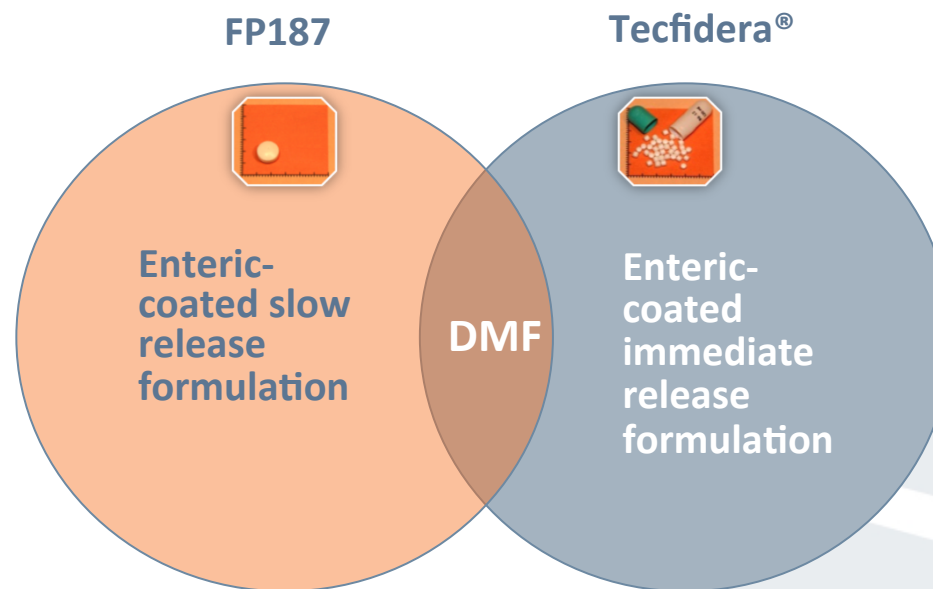


- Focused on DMF since 2004
- FP187: Proprietary slow release formulation of DMF
- 480 mg daily dose in MS patent application allowable and '871 patent interference declared
- MS NDA-enabling Phase 3 trial: 1 trial, 1 year endpoint
- IPO priced 10/14/2014, raised \$235 M in gross proceeds
- Well capitalized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

# FP187 Clinical Differentiation

- Same active pharmaceutical ingredient as Tecfidera® but new formulation may improve tolerability
- FP187 utilizes an “erosion matrix”

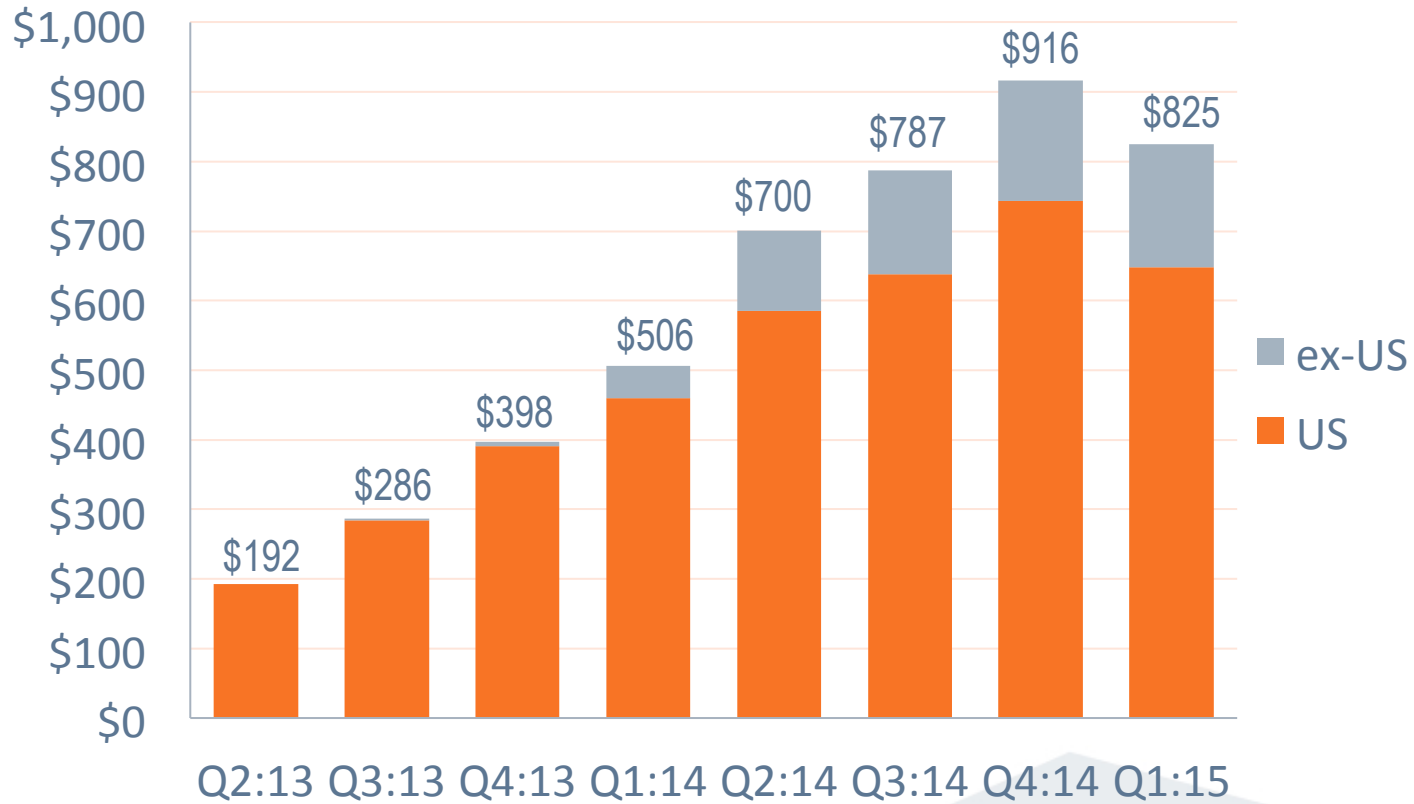
## Formulation Differentiation



# Tecfidera® RR-MS Global Sales



\$US mln



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

Source: Biogen Idec

# USPTO and EPO Claims Covering 480 mg/day



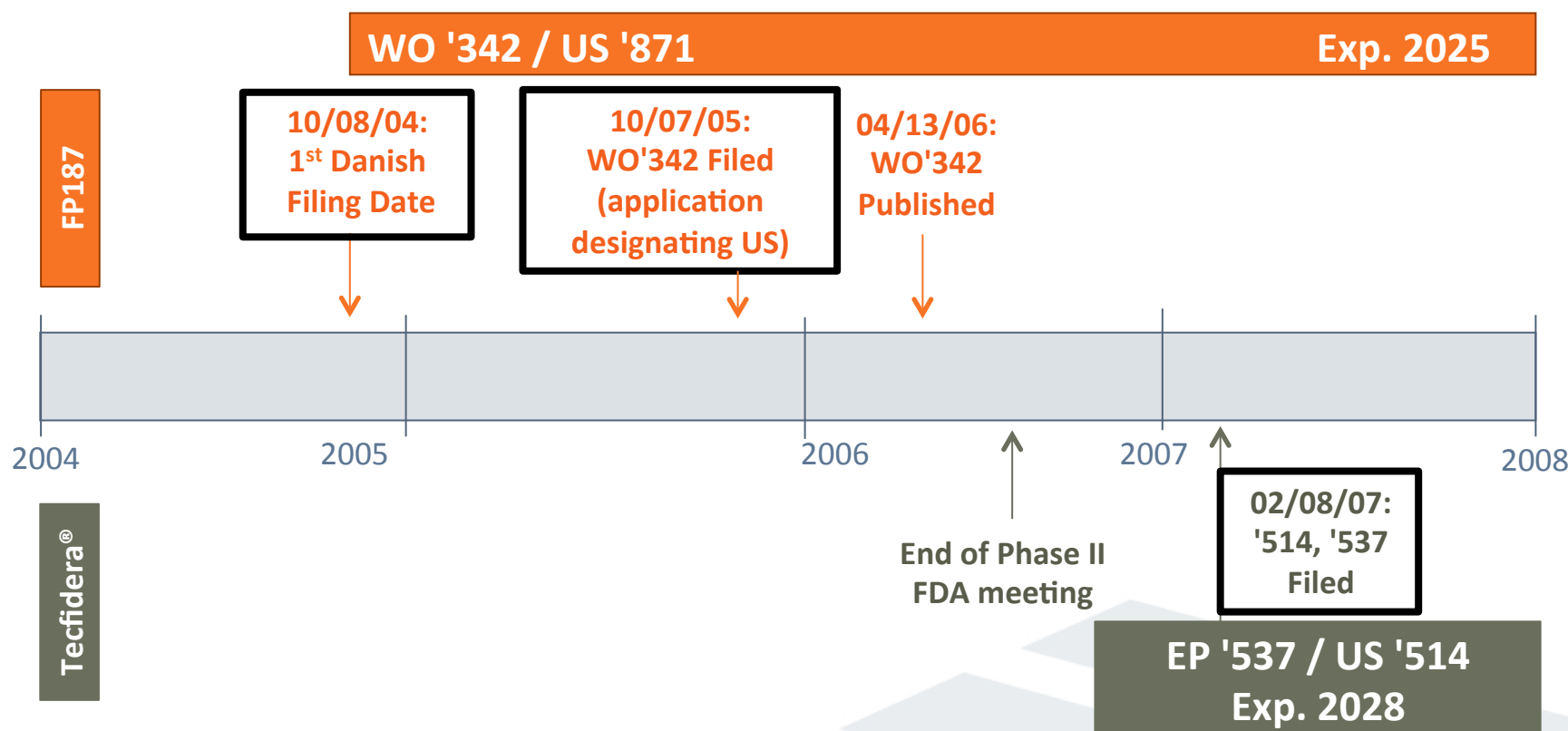
## 6 separate patent applications with claims to 480 mg/day with the same priority date of October 7, 2005

	Application Number	Description
US	11/576,871	Treating MS with DMF at 480 mg/day <b>* Interference declared; FWP as Senior Party – 4/13/15</b>
	14/213,399	Up-titration of DMF to 480 mg/day doses for the treatment of MS
	14/212,503	Treating MS with DMF at 480 mg/day to reach certain MMF levels in the bloodstream
European	EP14172398.1	Treating MS with 480 mg/day of DMF wherein the pH controlled release compositions have an enteric coat <b>* Decision to grant – 4/24/15</b>
	EP14172396.5	Treating MS with 480 mg/day of controlled release DMF
	EP14172390.8	Treating MS with 480 mg/day of controlled release DMF with particular in vitro dissolution profile

# Forward Pharma Detailed Timeline: 2004-2008



FP187 core composition patents 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**

Average length is 13 months to resolution, excluding appeals

## Motions Phase (~1 yr)

Three-judge panel at PTAB decides any patentability and senior party issues



## Priority Phase (~1 yr)

Three-judge panel gives final judgment on priority



## Resolution

## Resolution

Average Time to Resolution:  
13 months, excluding appeals

## Senior vs. Junior Party

- **Forward Pharma: “Senior Party”**

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

- **Biogen: “Junior Party”**

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

USPTO asked that at the initial conference call, “Biogen should be prepared to discuss how it expects to prevail in the interference.”

# 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**
- **Latest filing date: 10/07/05**

## 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**

# Schedule for the Interference

- May 22, 2015: Each party files and serves a list of motions the party intends to file
- May 29, 2015: Initial conference call to discuss the interference
- July 10, 2015: File authorized motions and file priority statements
- July 31, 2015: File authorized responsive motions
- September 11, 2015: File oppositions to all motions
- October 23, 2015: File all replies
- November 23, 2015: File request for oral argument, motions to exclude and observations
- December 21, 2015: File oppositions to motions to exclude evidence and file response to observations
- January 9, 2016: File replies to oppositions to motions to exclude
- January 16, 2016: File exhibits and sets of motions
- January 22, 2016: Default oral argument

## 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

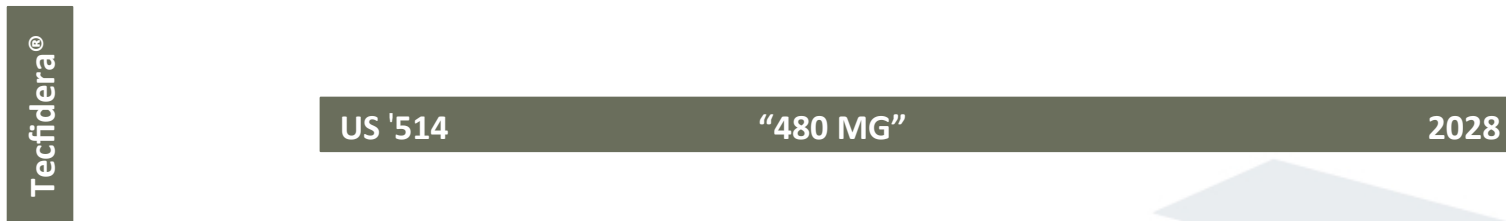
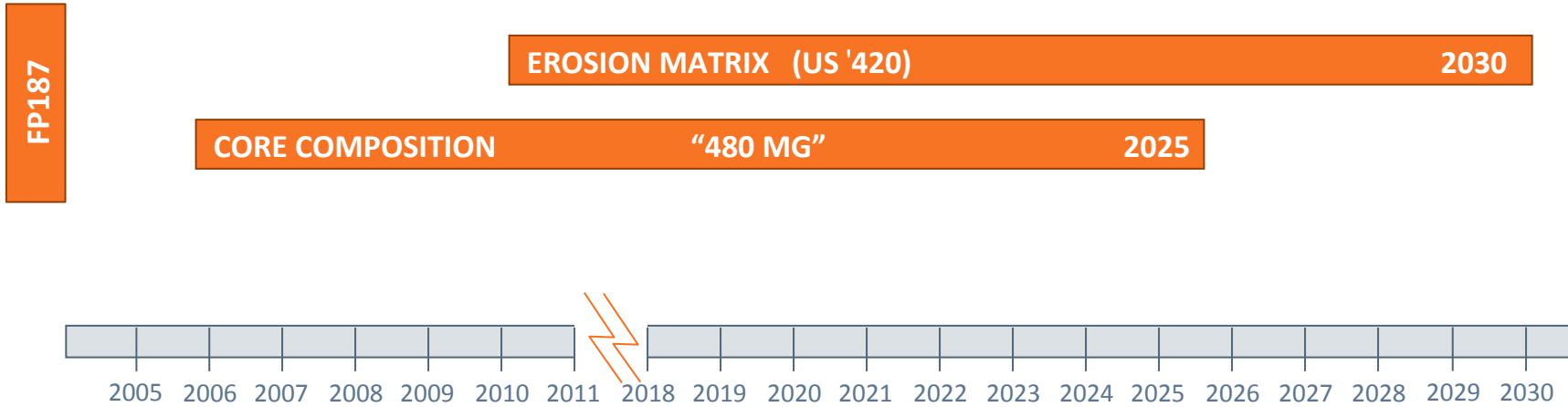
- Patentee who wins infringement case is entitled to no less than a “reasonable royalty”
- Legal framework:
  - Hypothetical negotiation between willing licensor and willing licensee on the eve of infringement
    - What is the maximum the infringer would pay the patentee to be able to stay on the market
    - 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

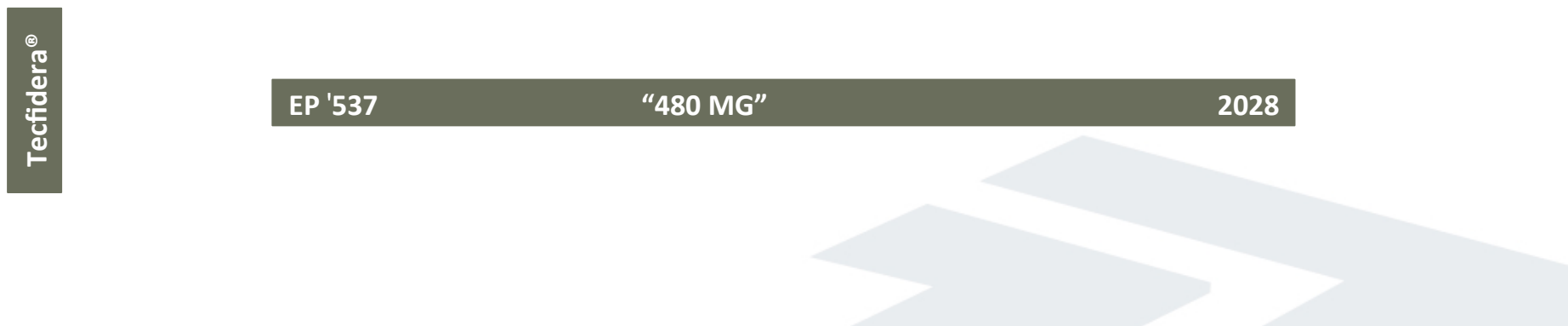
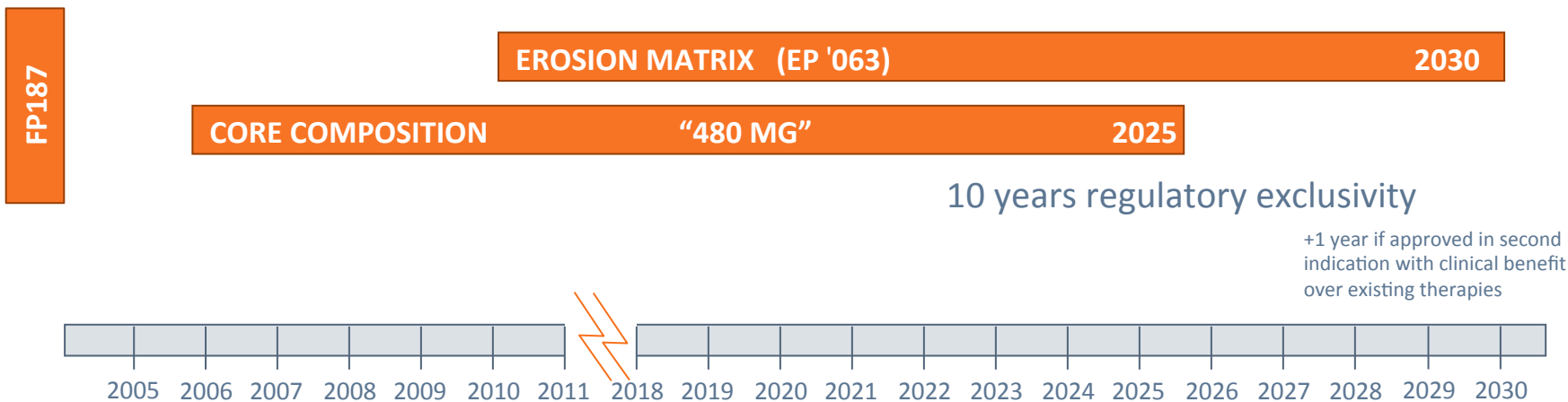
	Academic Inventor	Industrial Inventor
Competitive Product	NO	YES
Active R&D Spend	NO	YES
Ability to Commercialize	NO	YES
Opportunity Cost	LOW	HIGH
Royalty	LOW	HIGH
Example	Cabilly	Late-stage Biotech Deals



# Potential FP187 Patent Protection in the US



# Potential FP187 Patent Protection in Europe



# USPTO and EPO Claims Covering 480 mg/day



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

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## Other Intellectual Property

- EP2316430 ('430) Patent
  - Granted with oral hearing June 24 – 25th, 2015 at EPO
- Erosion Matrix Patent Family
  - US and EU patents covering FP187

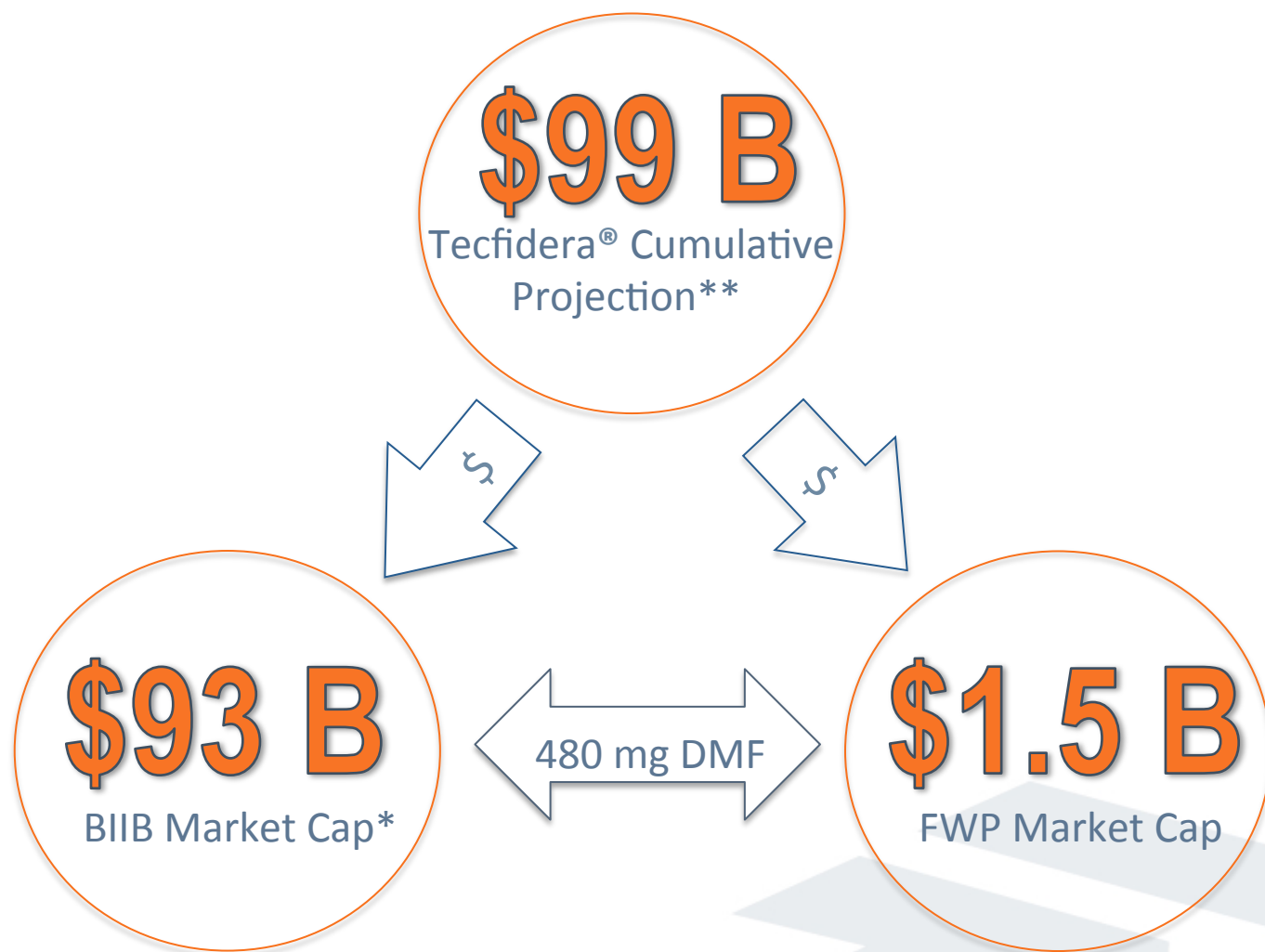
## German Utility Model

- Forward Pharma filed a lawsuit against BIIB on November 18, 2014
- Alleges infringement by Biogen's marketing of Tecfidera® in Germany with a label instructing a daily dose of 480 mg for MS
- An oral proceeding is scheduled for February 16, 2016 at the Regional Court in Dusseldorf

## Support for our IP

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

# BIIB to FWP Current Relative Valuation

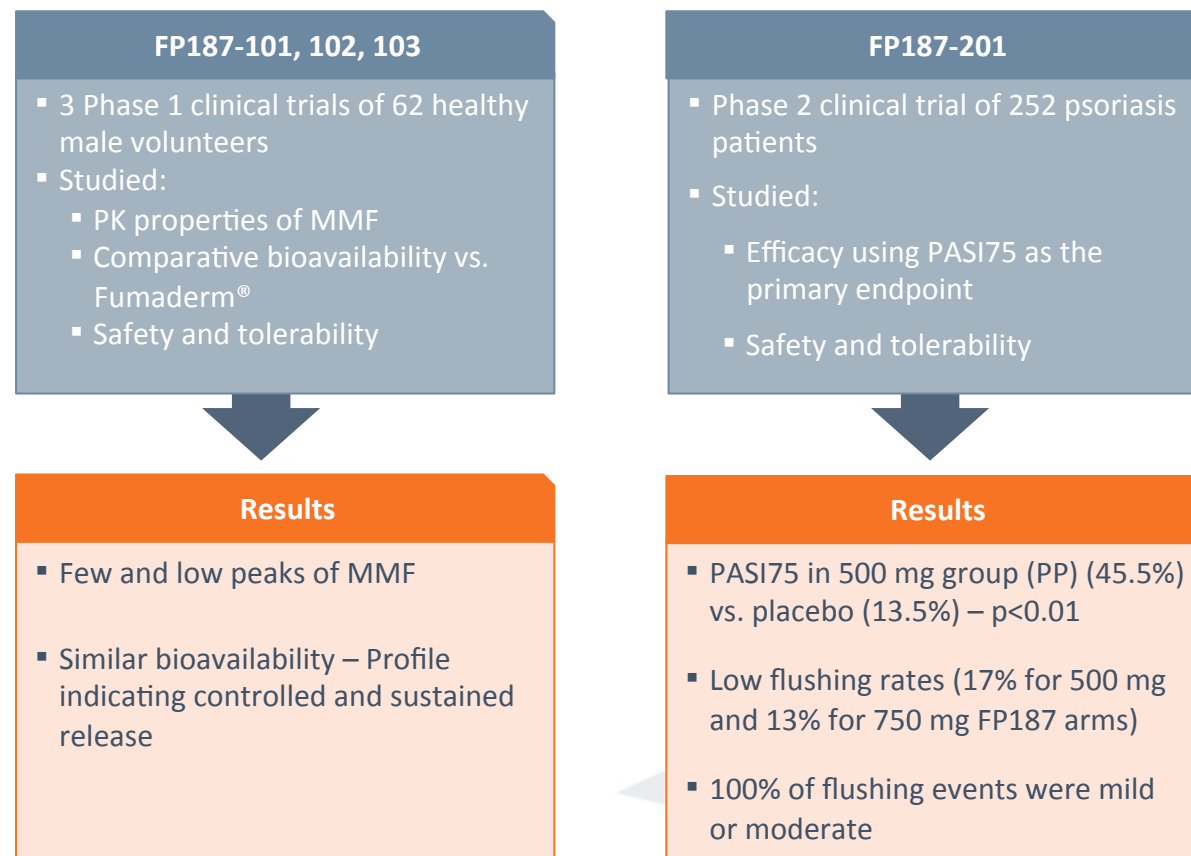


\* As of 5/12/15

\*\*Leerink estimates 2013 – 2028

318 patients treated to date with FP187

## Clinical Trials to Date



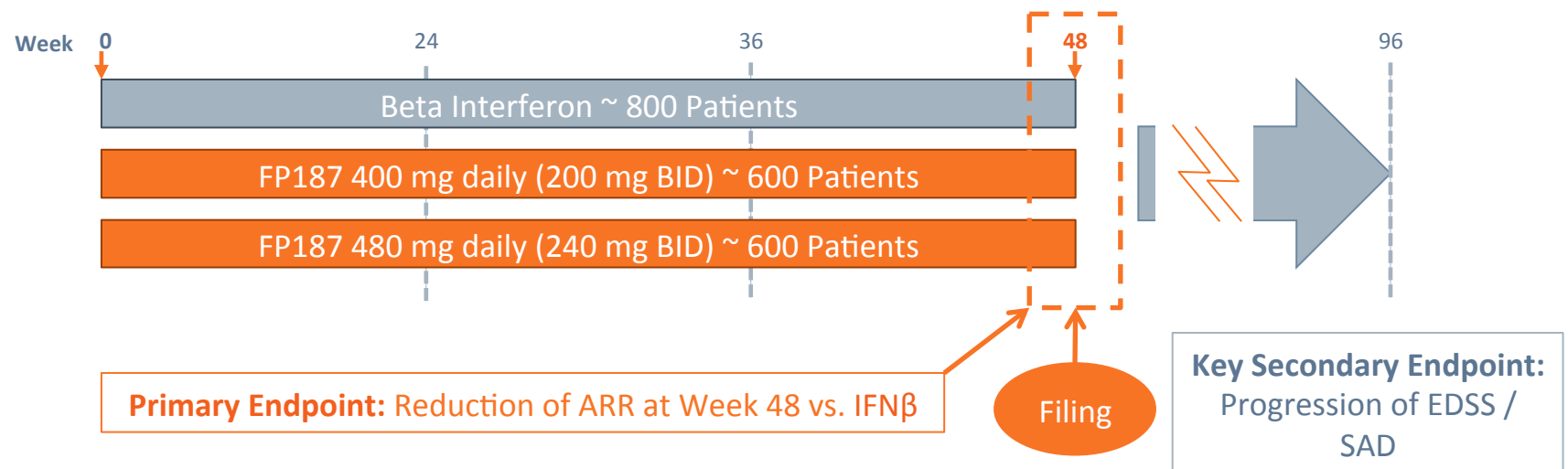


# Planned Phase 3 Trial in RR-MS (FDA Meeting August 2013): FP187-MS-301



## 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 (\$)**

**3/31/15**

Cash and Cash Equivalents

\$206.4 M

**Income Statement (\$ in thousands)**

**Quarter Ended  
March 31, 2015**

R&D Expenses

\$4,320

G&A Expenses

4,069

Operating Loss

\$8,389

## 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
- **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

## 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

## 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**

## IP Key Upcoming Events

- May 20, 2015 '8.1 EU Patent Application: Expected issuance
- June 24/25<sup>th</sup>, 2015 '430 Patent: EPO opposition oral hearing
- July 10, 2015 '871 Interference: File authorized motions and priority statements
- September 11, 2015 '871 Interference: File oppositions to motions
- January 22, 2016 '871 Interference: Default oral argument
- February 16, 2016 German Utility Model: Oral proceeding scheduled

## 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