# FP187: DMF in Multiple Sclerosis

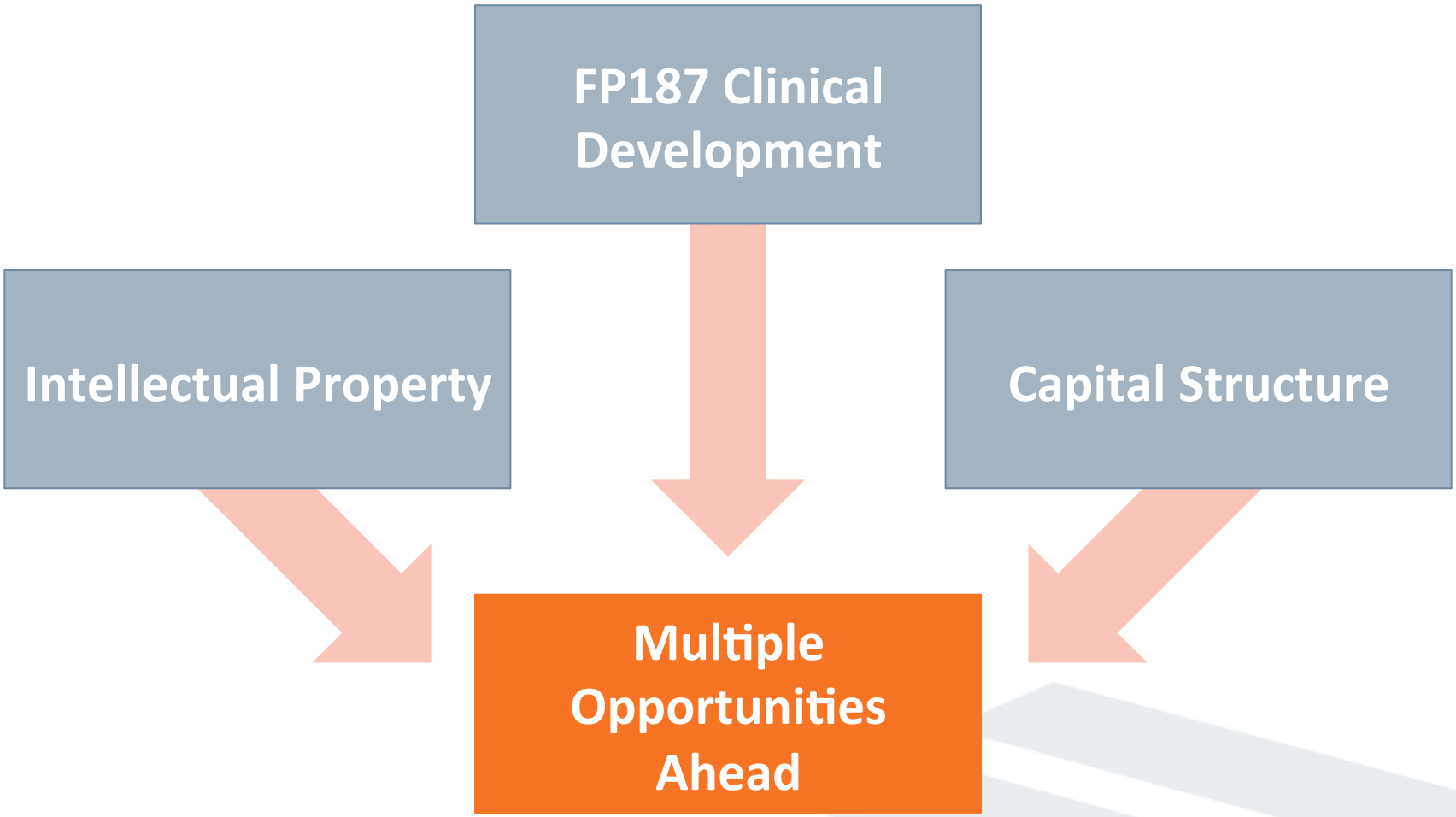
BioCentury Future Leaders Conference

March 20, 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



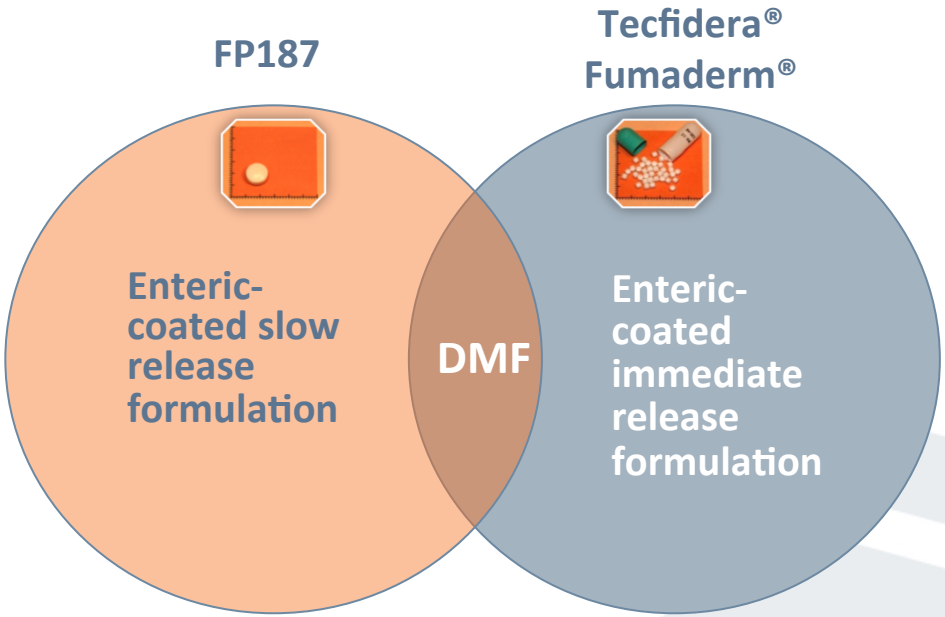
# Introduction to Forward Pharma

- Focused on DMF since 2004
- FP187: Proprietary slow release formulation of DMF
- 480 mg daily dose in MS patent application allowable
- 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

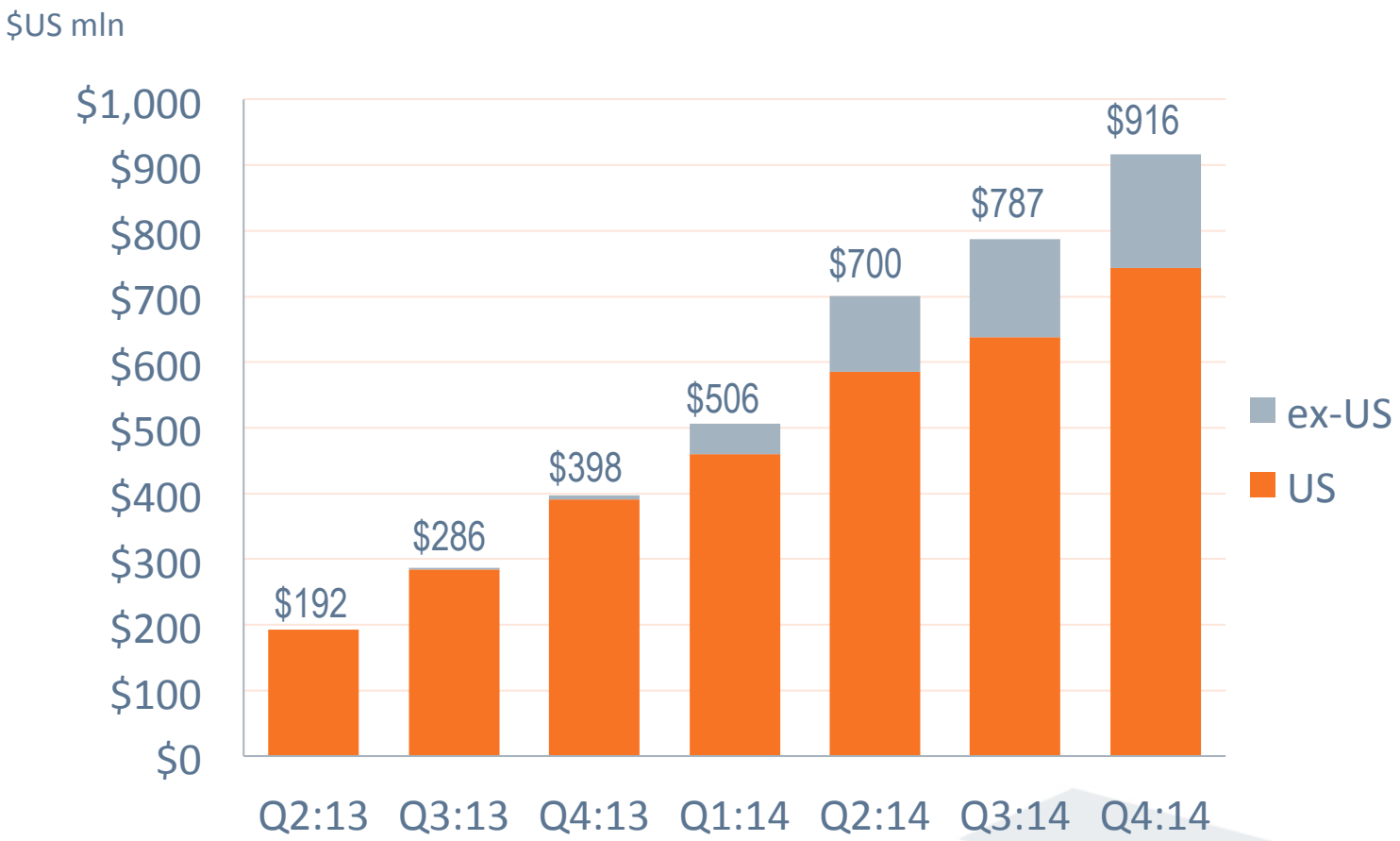
# FP187 Clinical Differentiation

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

## Formulation Differentiation



# Tecfidera® RR-MS Global Sales

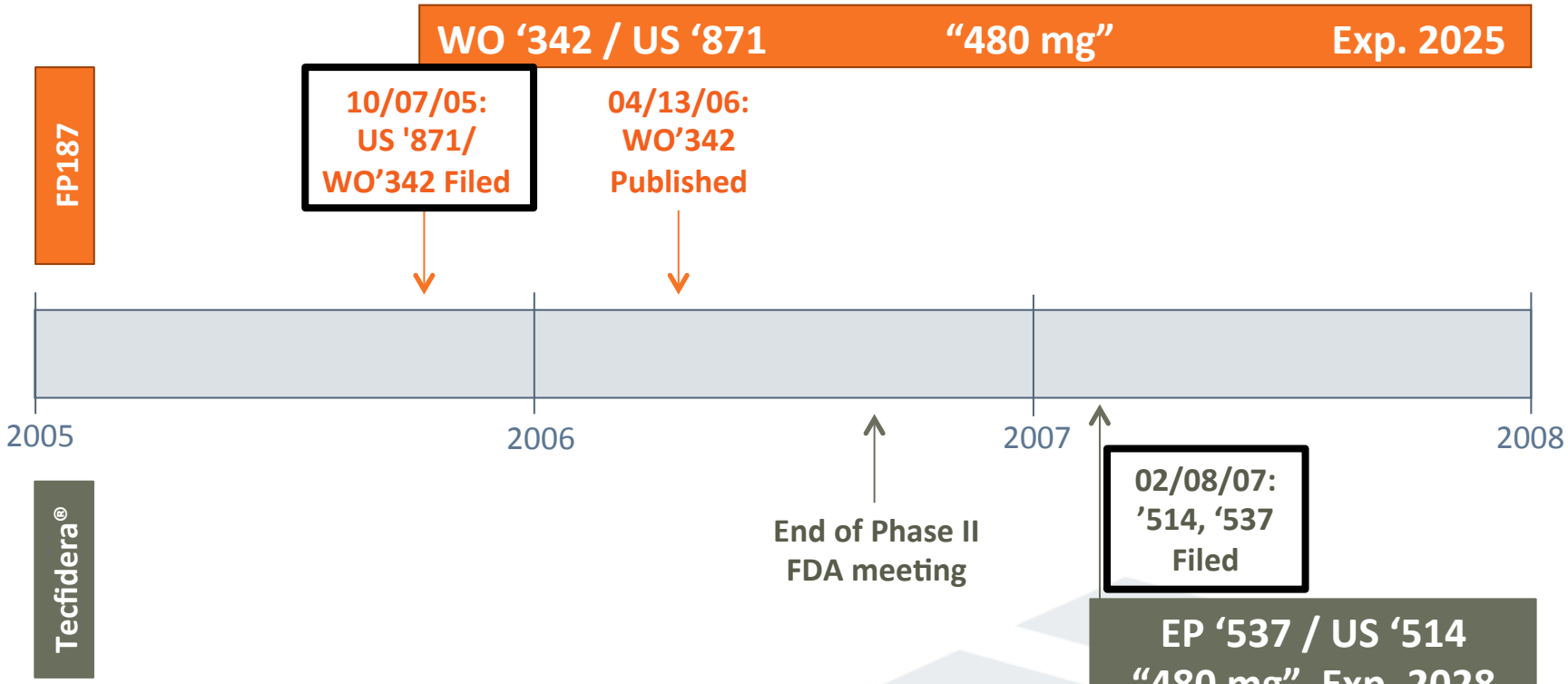



* 480 mg/day is the only approved dose for RR-MS

Source: Biogen Idec

# Forward Pharma Detailed Timeline: 2005-2008

## FP187 core composition patents filed 1 year, 4 months, 1 day earlier



# 480 mg/day:
# Forward Pharma '871 and Biogen Idec '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: 10/07/05**

## 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**
- **Filing date: 02/08/07**

# USPTO Interference Proceeding

- **Interference**

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

- **"Senior Party"**

  Has the earliest effective filing date to the common invention; entitled to the presumption that it is the first inventor

- **Average interference proceeding length**

  13 months to resolution, excluding appeals

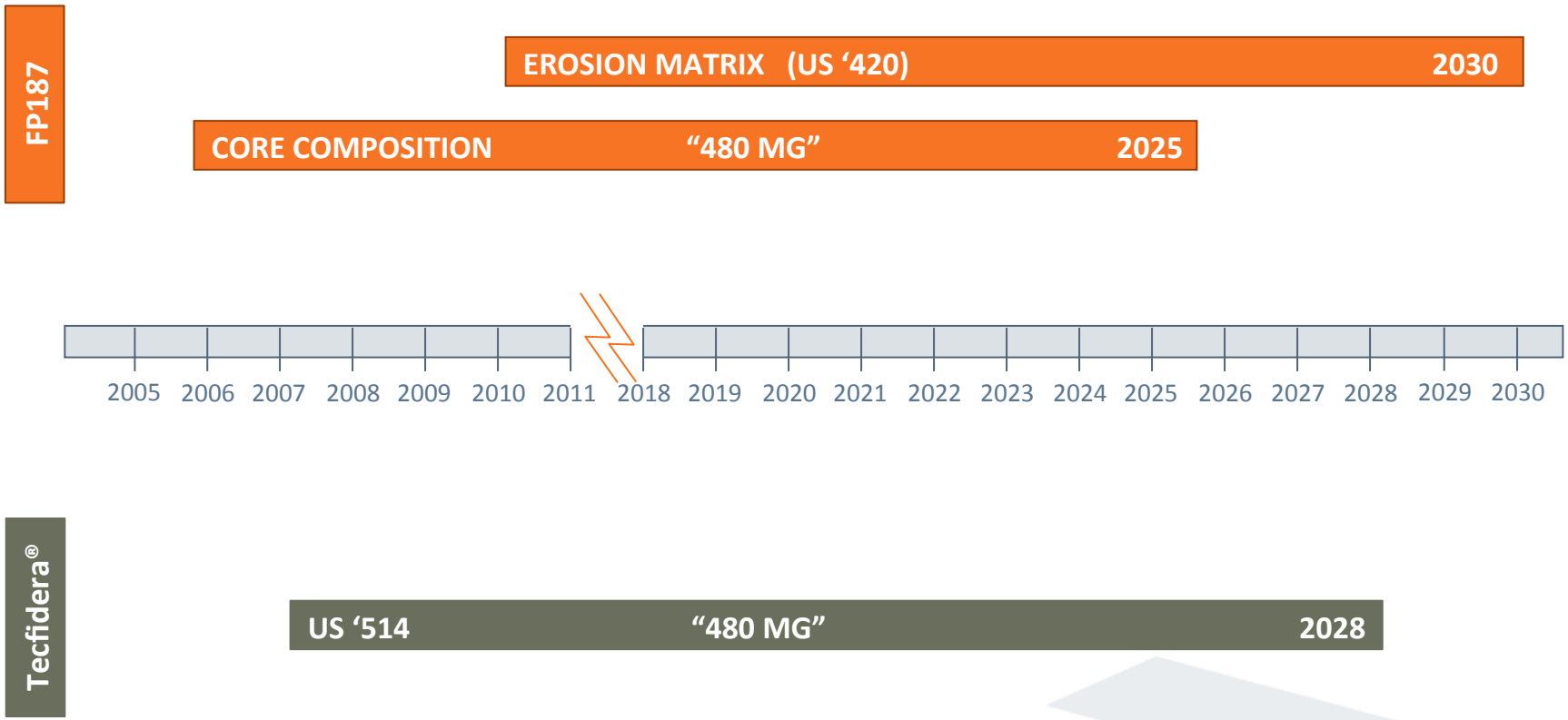
**Initial USPTO input: recommendation for Forward Pharma as senior party**

# USPTO and EPO Claims Covering 480 mg/day

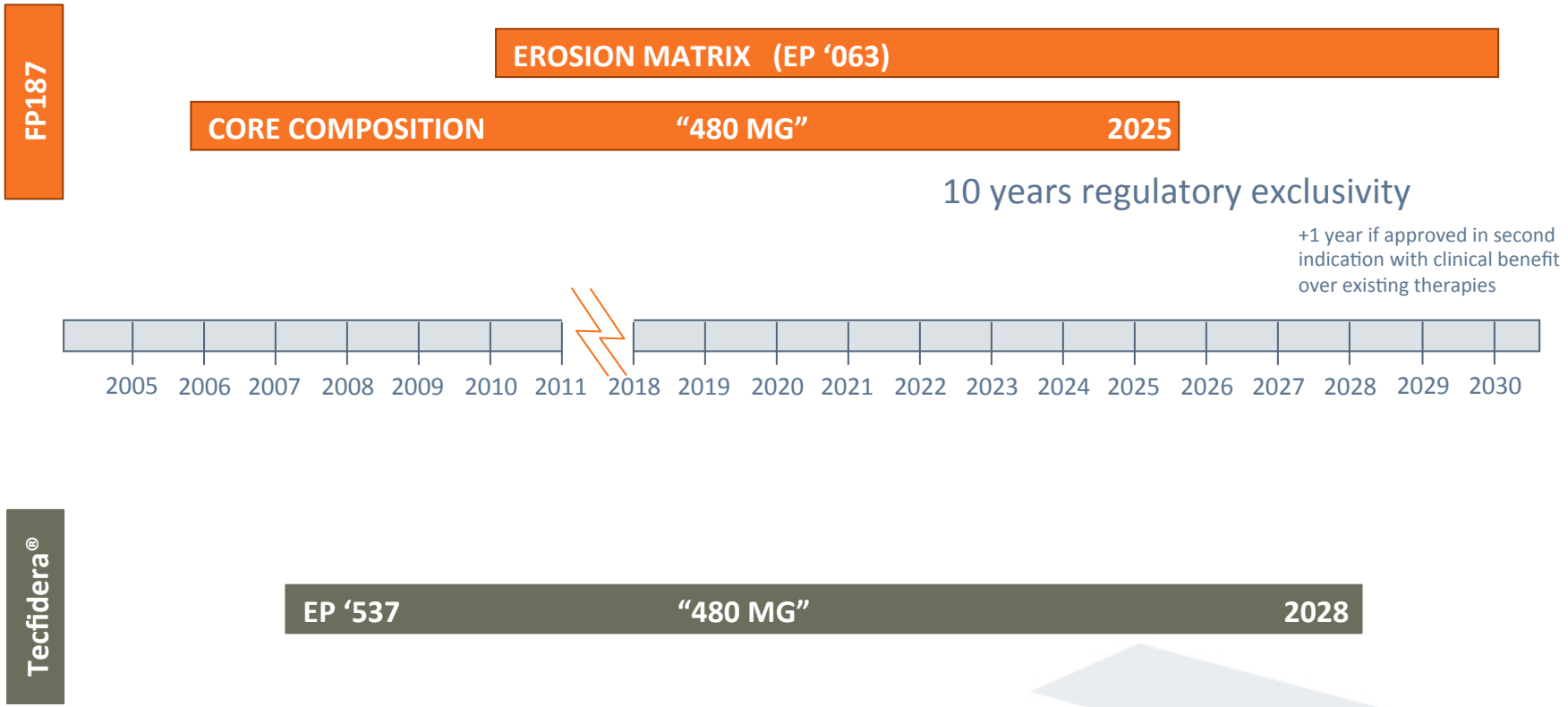
## 6 separate patent claims to 480 mg/day with the same priority date of October 7, 2005

| | Application Number | Description |
|---|---|---|
| US | 11/576,871 | Treating MS with DMF at 480 mg / day |
| | 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 | EP14172390.8 | Treating MS with 480 mg/day of controlled release DMF with particular in vitro dissolution profile |
| | EP14172396.5 | Treating MS with 480 mg/day of controlled release DMF |
| | EP14172398.1 | Treating MS with 480 mg/day of DMF wherein the compositions have an enteric coat |

# Potential FP187 Patent Protection in the US



# Potential FP187 Patent Protection in Europe



# Support for our IP

- **US:** USPTO has twice found allowable 480 mg/day as an invention; previously recommended for an interference
- **Europe:** Inventive step opinion
- **Competitors:** References to our 480 mg/day patent applications as prior art in opposition proceedings against Biogen Idec in Europe

# BIIB to FWP Current Relative Valuation


* As of 3/18/15

**Leerink estimates 2013 – 2028

# FP187 Clinical Strategy

## 318 patients treated to date with FP187

### 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

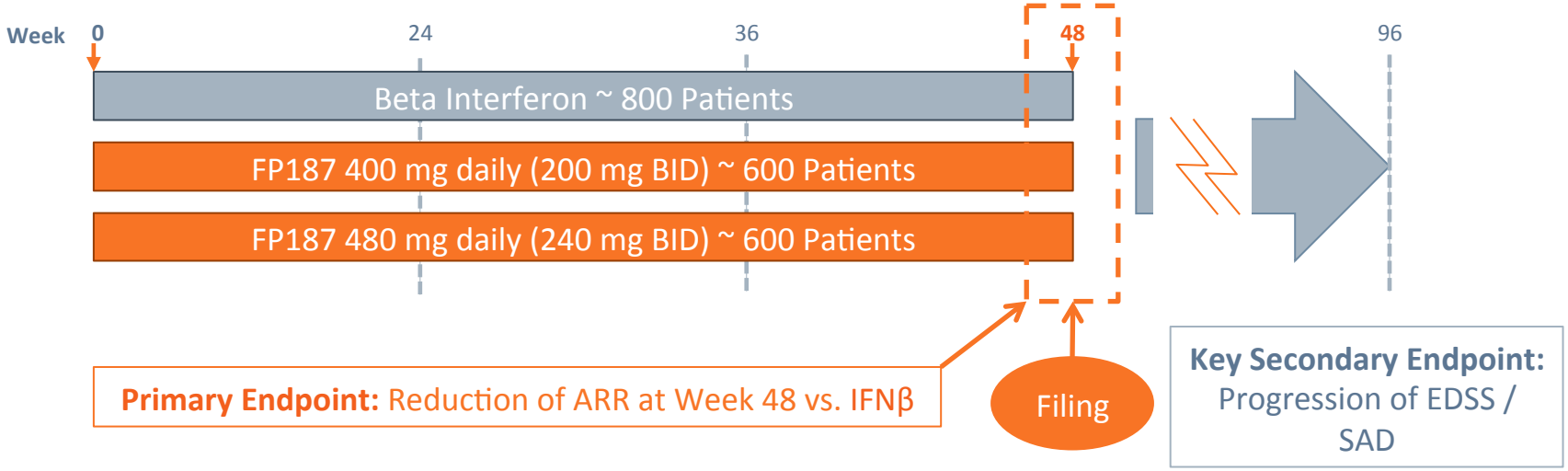
**Results**

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

# 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 ($)*** | **Pro Forma 09/30/14*** |
|---|---|
| **Cash and Cash Equivalents** | $236 M |

| ***Income Statement ($ in thousands)*** | **First 9 months 2014** |
|---|---|
| **R&D Expenses** | $6,616 |
| **G&A Expenses** | 5,156 |
| **Operating Loss** | $11,772 |

*Pro Forma 9/30/14 adjusts actual cash and cash equivalents at 09/30/14 for the receipt of $219 million in net proceeds after underwriting discount from the IPO.

# Corporate 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
- **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**

# Key Upcoming Events

- Interference proceeding initiation 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

# Analyst Coverage

| Firm | Analyst |
|---|---|
| Citigroup | Yaron Werber |
| Jefferies | Thomas Wei |
| JMP Securities | Jason N. Butler, PhD |
| Leerink Partners | Jason Gerberry, JD |
| RBC Capital Markets | Michael Yee |

# Summary

- Focused on DMF since 2004
- FP187: Proprietary formulation of DMF
- 480 mg daily dose in MS patent application allowable
- MS NDA-enabling Phase 3 trial: 1 trial, 1 year endpoint
- Well capitalized with over $200 million in cash