ARENA PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

Filed 07/10/17 for the Period Ending 07/10/17

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 10, 2017

Arena Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**000-31161**	**23-2908305**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
6154 Nancy Ridge Drive, San Diego, CA		**92121**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (858) 453-7200

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

In this report, “Arena Pharmaceuticals,” “Aren a,” “Company,” “we,” “us” and “our” refer to Arena Pharmaceuticals, Inc., and/or one or more of our wholly owned subsidiaries, unless the context otherwise provides. Arena Pharmaceuticals® and Arena® are registered service marks of Arena Pharmaceuticals, I nc.

Item 7.01 Regulation FD Disclosure.

The slides attached as Exhibit 99.1 to this Current Report contain certain additional information related to the clinical data results discussed in Item 8.01 below as well as updates to the Company’s program pipeline. The Company intends to present the slides during a conference call and live webcast with the investment community on July 10, 2017, at 4:30 p.m. EDT.

The information contained in this Item 7.01, including in Exhibit 99.1 hereto, is being “furnished” and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, is not subject to the liabilities of that section and is not deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

Topline Phase 2 Results for Ralinepag

On July 10, 2017, the Company announced positive Phase 2 results for ralinepag, an investigational, long-acting, orally administered prostacyclin receptor agonist under development for the treatment of pulmonary arterial hypertension (PAH). In this 61-patient study, the primary efficacy analysis demonstrated a statistically significant absolute change from baseline in pulmonary vascular resistance (PVR) compared to placebo. Ralinepag also demonstrated numerical improvement in 6-minute walk distance (6MWD).

Ralinepag improved median PVR by 163.9 dyn.s.cm-5 from baseline compared to a 0.7 dyn.s.cm-5 worsening from baseline in the placebo arm (P=0.02). Patients treated with ralinepag had a 29.8% improvement in PVR compared to the placebo arm (P=0.03) and a 20.1% improvement in PVR compared to baseline. Additionally, adverse events observed in the study were consistent with other prostacyclin treatments for the management of PAH, with headache, nausea, diarrhea, jaw pain and flushing being the most commonly reported adverse events. The Company plans to present full study results at future medical congresses.

The Phase 2 study was a randomized, double-blind, placebo-controlled, dose-ranging study in 61 adult patients with PAH, WHO/NYHA functional class II-IV. Study medication was titrated over 9 weeks, followed by a 13-week treatment period. The primary efficacy analysis was absolute change from baseline in PVR at week 22. Additional endpoints included change from baseline in 6-minute walk test, proportion of subjects who exhibit clinical worsening and safety and tolerability. Patients who completed week 22 could transition to an open-label ralinepag extension study.

Ralinepag (APD811) is an oral, next-generation, selective IP receptor agonist targeting the prostacyclin pathway and intended for the treatment of PAH. The Company discovered and developed this drug candidate internally. Ralinepag is an investigational compound that is not approved for any use in any country.

Item 9.01 Financial Statements and Exhibits. *(d) E*
xhibits.

Exhibit No.	Description
99.1	Slide presentation dated July 10, 2017, titled “Ralinepag Phase 2 Clinical Results.”

Forward-Looking Statements

Statements in this report on Form 8-K that are not statements of historical fact are forward-looking statements, which involve a number of risks and uncertainties. Such statements include statements about the Company’s plans to present full study results; transitioning patients to an open-label extension study; ralinepag’s potential; and other statements that are not historical facts, including statements that may include the words “plans” and “could”. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from our expectations. Factors that could cause actual results to differ materially from the forward-looking statements include the following: top-line data may not accurately reflect the complete results of a particular study or trial; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical and nonclinical data is voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than Arena or others, request additional information, have additional recommendations or change their guidance or requirements; the timing and outcome of research, development and regulatory review is uncertain; we expect to need additional funds to advance all of our programs, and you and others may not agree with the manner we allocate our resources; our drug candidates may not advance in development or be approved for marketing; risks related to developing, seeking regulatory approval and commercializing drugs; unexpected or

unfavorable new data; Arena's and third parties' intellectual property rights; clinical trials and other studies may not proceed at the time or in the manner expected or at all; data and information related to our programs may not meet regulatory requirements or otherwise be sufficient for further development, regul atory review, partnering or approval; competition; risks related to commercializing drugs, including regulatory, manufacturing, supply and marketing issues and their availability and use; reimbursement and pricing decisions; risks related to relying on par tners and other third parties; and satisfactory resolution of litigation or other disagreements; and those factors disclosed in Arena's filings with the Securities and Exchange Commission, including our Form 10-Q for the quarter ended March 31, 2017 . These forward-looking statements represent our judgment as of the time of this report on Form 8-K. We disclaim any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: July 10, 2017

Arena Pharmaceuticals, Inc.

By: /s/ Amit D. Munshi
Amit D. Munshi
President and Chief Executive Officer

Exhibit Index

Exhibit Number	Description
99.1	Slide presentation dated July 10, 2017, titled “Ralinepag Phase 2 Clinical Results.”

Exhibit 99.1

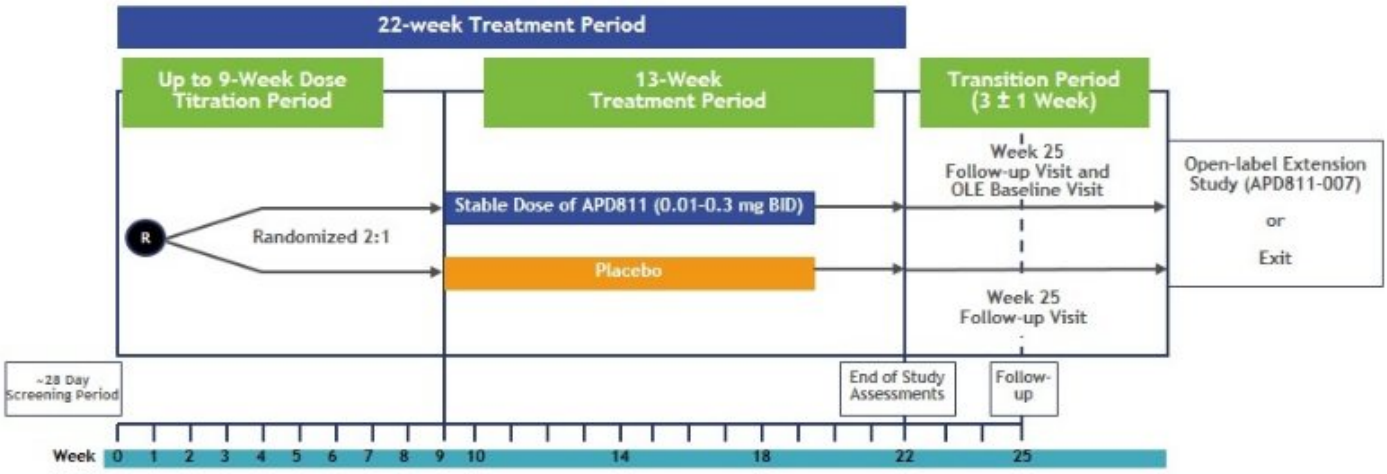
ARENA PHARMACEUTICALS

Forward-Looking Statements

This presentation includes forward-looking statements that involve a number of risks and uncertainties, including statements about our investigative stage drug candidate, ralinepag, including its potential to become best-in-class, profile and phase 3 and development planning; our pipeline of drug candidates; expected data readouts and initiation of new clinical trials; our focus, goals, strategy, plans, timelines and guidance; and other statements that are not historical facts, including statements that may include words such as "may," "will," "intend," "plan," "expect," "potential" or other similar words. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from expectations, and you are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time they were made. Factors that could cause actual results to differ materially from such statements include, without limitation: top-line data may not accurately reflect the complete results of a particular study or trial; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical and nonclinical data is voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than Arena or others, request additional information, have additional recommendations or change their guidance or requirements; the timing and outcome of research, development and regulatory review is uncertain; we expect to need additional funds to advance all of our programs, and you and others may not agree with the manner we allocate our resources; our drug candidates may not advance in development or be approved for marketing; risks related to developing, seeking regulatory approval and commercializing drugs; unexpected or unfavorable new data; Arena's and third parties' intellectual property rights; clinical trials and other studies may not proceed at the time or in the manner expected or at all; data and information related to our programs may not meet regulatory requirements or otherwise be sufficient for further development, regulatory review, partnering or approval; competition; risks related to commercializing drugs, including regulatory, manufacturing, supply and marketing issues and their availability and use; reimbursement and pricing decisions; risks related to relying on partners and other third parties; and satisfactory resolution of litigation or other disagreements. Additional factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements are disclosed in our SEC filings, including under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017. We disclaim any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

Ralinepag Phase 2 Randomized, Placebo-Controlled Trial in WHO Group 1 PAH

61 pts with PAH (2:1) - Evaluated efficacy, safety/tolerability and PK



APD811 = Ralinepag-IR; 6MWD, 6-minute walk distance; BID, twice daily; OLE, open-label extension; PAH, pulmonary arterial hypertension; PK, pharmacokinetic; PVR, pulmonary vascular resistance; WHO, World Health Organization

Pre-specified Endpoints

1. PVR primary endpoint: Absolute change from baseline
   - Primary efficacy analysis testing trial hypothesis
   - Primary statistical test (2-sided, 0.05 alpha); subsequent testing without adjustment for multiplicity
   - Log-transformation and geometric mean ratio (GMR) expressed as GMR percentage change over baseline
2. PVR secondary endpoint: Percent change from baseline
3. 6MWD endpoint: Absolute change from baseline

ANCOVA adjustment for endpoint baseline, WHO/NYHA functional class, and background ERA therapy

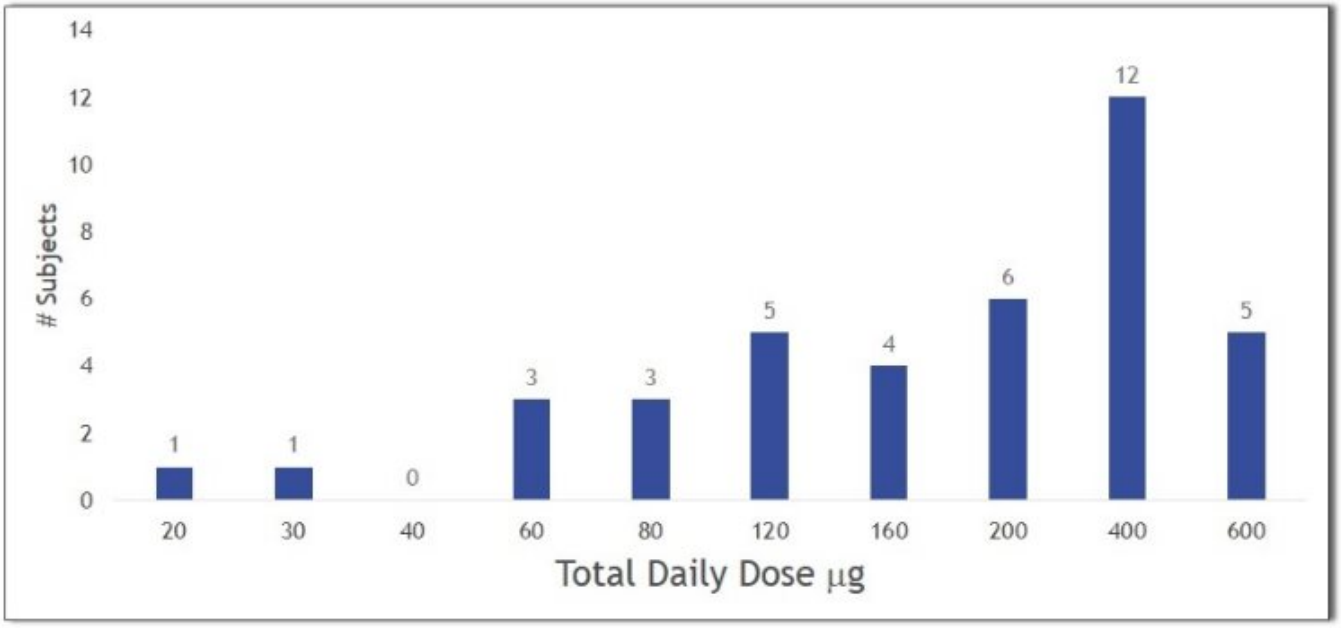
Baseline Characteristics

	Placebo (n=21)	Ralinepag (n=40)
Mean Age, Years	55.6	46.2
Sex, n (%)		
Male	1 (4.8)	7 (17.5)
Female	20 (95.2)	33 (82.5)
Race, n (%)		
White	19 (90.5)	38 (95)
Other	2 (9.5)	2 (5)
Mean PVR, dyn·s·cm^{-5}	598	780
Median PVR, dyn·s·cm^{-5}	480	705
Mean 6MWD, m	351	393
WHO FC, %		
II	57.1	55.0
III	42.9	42.5
IV	0	2.5
Background PAH therapy, %		
Monotherapy	52	35
Combination Therapy	48	65
New PAH therapy started within 6 months before Day 1, %*	38	12.5

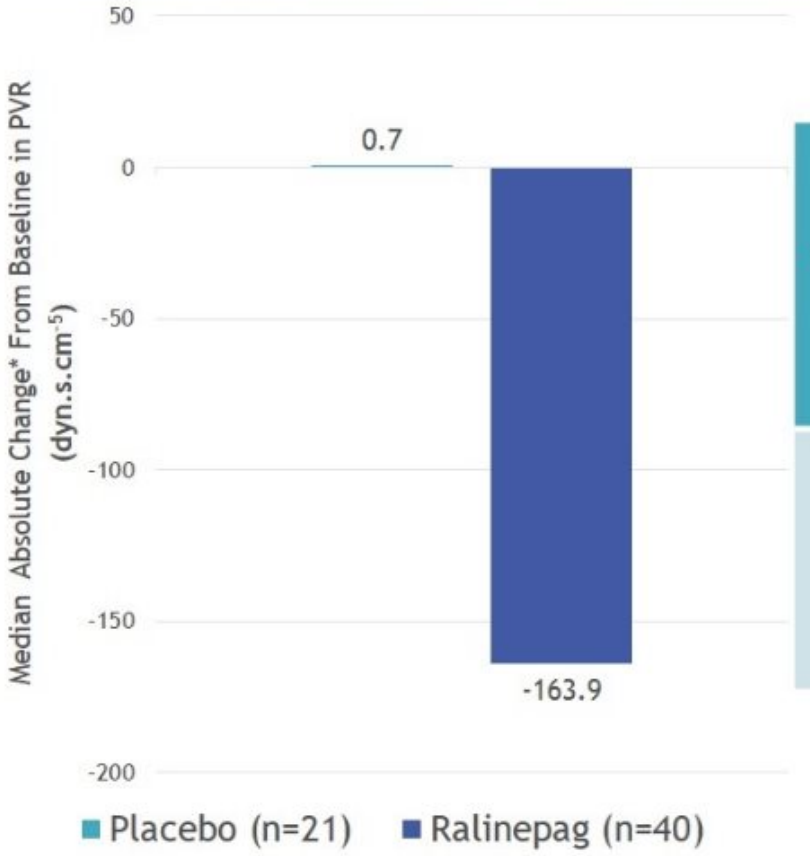
* Post-hoc definition

Distribution of Maintenance Dose

57.5% of patients achieved a total daily dose of 200 μg or higher



1) Ralinepag Significantly Improved Pulmonary Vascular Resistance (PVR); ITT Population

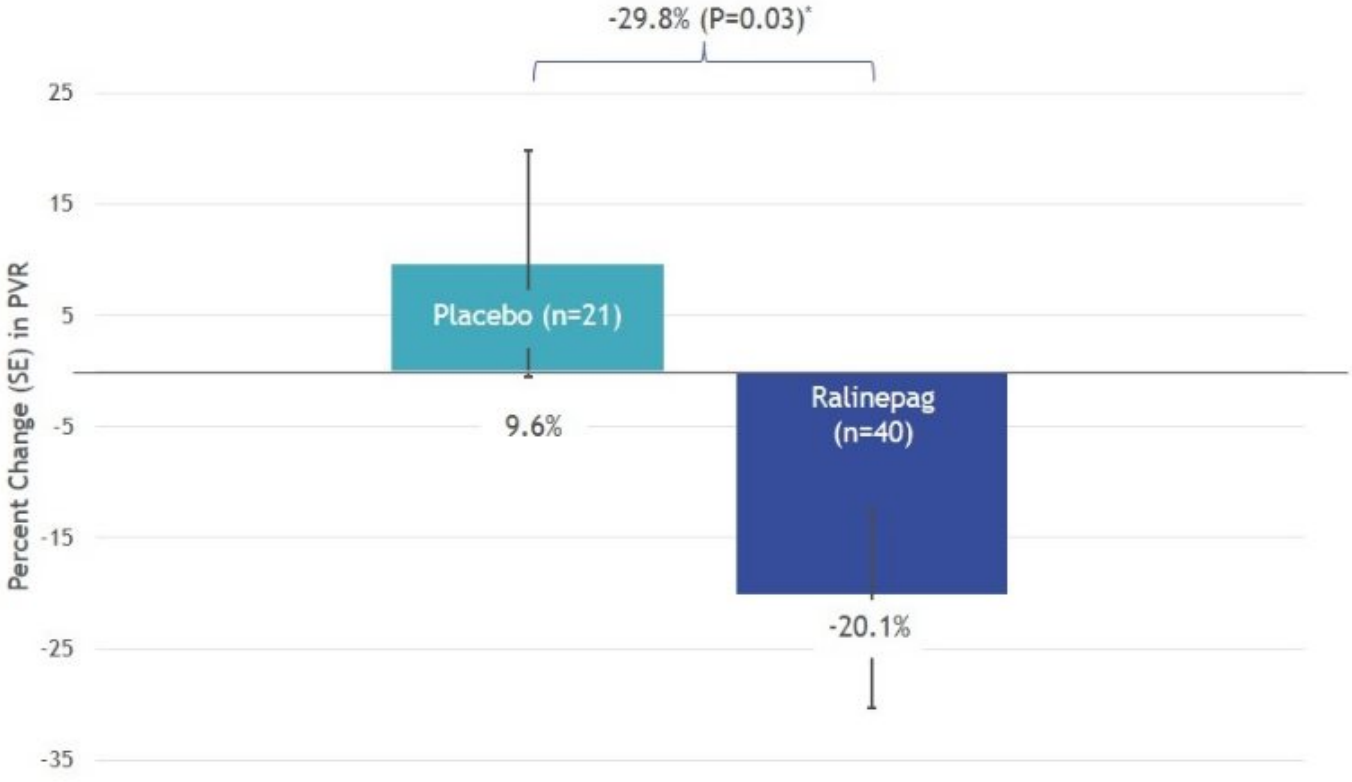


Primary Endpoint: Change in PVR Geometric Mean Ratio (GMR) [Expressed as Percent Change]**

Treatment Effect Comparison	-25.8% over placebo (p=0.02)

*Median change used due to non-normal distribution; mean absolute change from baseline: placebo 25.5, ralinepag -175.7 dyn.s.cm^{-5}
**Within-group GMR % change: placebo -0.4%, ralinepag -26.1%

2) Ralinepag Reduced PVR by 29.8% from Baseline Compared with Placebo; ITT Population



*Least squares mean change from placebo; non-parametric test to account for non-normal distribution

3) 6 Minute Walk Distance (6MWD)

Clinically Meaningful Improvement for Ralinepag-Treated Patients

- Ralinepag group increased by 36.2m from baseline (p=0.003)
- Placebo group increased by 29.4m from baseline (p=NS)
- Between group comparison directionally favors ralinepag (6.8m; p=NS)

Ralinepag Significantly Improved PVR and Increased 6MWD from Baseline

*PVR Least squares mean change; **6MWD = 6 minute walk distance - between group comparison not statistically significant

Safety and Tolerability

- The overall safety and tolerability profile of ralinepag was consistent with the known profile of the prostacyclin therapy class
- Adverse events that occurred most frequently on ralinepag were similar to the on-target effects expected for prostacylin therapies:
  - Headache, nausea, diarrhea, jaw pain, flushing
  - Events were more frequent during dose titration; consistent reduction in adverse event frequency during maintenance period
- During 25 week safety assessment period 12.5% of patients discontinued ralinepag and 10.0% patients discontinued placebo due to adverse events
- Serious adverse events occurred in 4 (10%) patients taking ralinepag and 6 (28.6%) patients taking placebo
  - 2 deaths occurred among placebo patients; 0 deaths on ralinepag

Successful Phase 2 Trial Results Inform Progression to Phase 3 Program

- Ralinepag Phase 2 trial results demonstrate meaningful efficacy among a contemporary PAH population
  - Majority of patients receiving background dual combination therapy
  - Ralinepag reduced median PVR by 163.9 dyn·s·cm^{-5} from a baseline of 705 dyn·s·cm^{-5}
  - Statistically significant improvement over placebo for both absolute change (geometric mean ratio) and percent change
  - Clinically meaningful numerical improvement in 6MWD
- Tolerability and adverse event profile consistent with the known effects of therapeutics in the prostacyclin class
  - Dose titration tolerated as expected
  - No increase in serious adverse events or death compared to placebo
- Phase 3 planning underway

Focus on Pipeline
Differentiated Assets with High-Value Potential

Program	Therapeutic Area/Indication	PC	P1	P2a	P2b	P3	Timing
Ralinepag *Potent IP Receptor Agonist*	Pulmonary Arterial Hypertension (PAH)						*P3 Preparations*
Etrasimod *Optimized Activity S1P Receptor Modulator*	Ulcerative Colitis (UC)						*P2 Data by YE 2017 / Q1 2018*
	Extra-Intestinal Manifestations (EIM) in Irritable Bowel Disease (IBD)						*Initiated P2*
	Pyoderma Gangrenosum (PG)						*Initiated P2*
	Primary Biliary Cholangitis (PBC)						*Initiate P2 in 2017*
APD371 *Highly Selective Full Agonist to CB_2*	Pain Associated with Crohn's Disease						*P2 Data by YE 2017 / Q1 2018*