

ARENA PHARMACEUTICALS INC

FORM 8-K (Current report filing)

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Address	6154 NANCY RIDGE DRIVE SAN DIEGO, CA 92121
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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): March 14, 2017

Arena Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-31161

(Commission File Number)

23-2908305
(IRS Employer
Identification No.)

**6154 Nancy Ridge Drive,
San Diego, CA**
(Address of Principal Executive Offices)

92121
(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))
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In this report, “Arena Pharmaceuticals,” “Arena,” “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, Inc.

Item 2.02 Results of Operations and Financial Condition .

On March 14, 2017, we issued a press release reporting our financial results for the fourth quarter and full year ended December 31, 2016. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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

99.1 Press release issued March 14, 2017, reporting financial results for the fourth quarter and full year ended December 31, 2016

Exhibit Index

Exhibit Number	Description
99.1	Press release issued March 14, 2017, reporting financial results for the fourth quarter and full year ended December 31, 2016



Arena Pharmaceuticals Provides Corporate Update and Reports Fourth Quarter and Full-Year 2016 Financial Results

- Clinical Data from Multiple Phase 2 Development Programs Expected in 2017 -

San Diego, CA – March 14, 2017 - Arena Pharmaceuticals, Inc. (Nasdaq: ARNA), a biopharmaceutical company focused on developing novel, small molecule drugs across multiple therapeutic areas, today provided a corporate update and reported financial results for the fourth quarter and full-year ended December 31, 2016.

“We are very pleased with our progress in 2016 as we have positioned the Company to deliver results on multiple Phase 2 programs in 2017. In the last nine months, since the arrival of the new management team, we prioritized our Phase 2 programs; strengthened our board and team to support our strategy; implemented cost reduction measures; renegotiated our agreement with Eisai; and took a methodical approach to maximizing the value of our assets,” said Amit Munshi, Arena’s President and CEO.

As previously disclosed, in February 2017, Arena appointed Jayson Dallas, M.D., Oliver Fetzer, Ph.D., and Garry A. Neil, M.D. as independent directors to the Company’s Board of Directors.

“This year we expect to report results from all three of our proprietary Phase 2 programs, beginning with ralinepag in mid-year for pulmonary arterial hypertension,” Mr. Munshi stated. “For etrasimod, we remain focused on maximizing the broad clinical utility of this compound in a time and cost effective manner. We are pleased to have initiated Phase 2 trials in both dermatologic extraintestinal manifestations in inflammatory bowel disease patients and pyoderma gangrenosum. We also plan to initiate a study in primary biliary cholangitis this year. Additionally, we have made important adjustments to the Phase 2 ulcerative colitis trial to ensure a robust data readout by year-end 2017.”

Pipeline Update

Ralinepag – oral, selective IP receptor agonist targeting the prostacyclin pathway for the potential treatment of pulmonary arterial hypertension (PAH)

- Phase 2 trial in PAH
 - Enrollment of the Phase 2 trial in pulmonary arterial hypertension was completed in December 2016
 - Data readout expected in mid-year 2017
- Phase 1 pharmacokinetic and pharmacodynamic trial comparing current twice-daily formulation with a new once-daily formulation in healthy volunteers
 - Trial initiated in March 2017
 - Data readout expected mid-year 2017

Etrasimod – orally available next generation sphingosine-1-phosphate (S1P) receptor modulator for the potential treatment of a number of autoimmune diseases

- Phase 2 trial in ulcerative colitis (UC)
 - Implementing protocol updates to the OASIS program that maintain study conduct, integrity, and patient safety; further the probability of a successful trial; and facilitate expected data readout in 2017
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- Phase 2 trial in dermatological extraintestinal manifestations (EIM) in patients with inflammatory bowel disease (IBD)
 - Trial initiated in March 2017
- Phase 2 trial in pyoderma gangrenosum (PG)
 - Trial initiated in March 2017
- Phase 2 trial in primary biliary cholangitis (PBC)
 - Intend to initiate clinical study in 2017

APD371 – orally available full agonist of the cannabinoid-2, receptor for the potential treatment of visceral pain, specifically pain associated with Crohn’s disease

- Phase 2 trial in pain associated with Crohn’s disease
 - Currently incorporating feedback related to study design and conduct into the clinical protocol design and selecting sites

Collaborations Update

- **Axovant**
 - On February 13, 2017, Axovant announced preliminary results from the planned interim analysis of the first 11 patients to complete its Phase 2 study of nelotanserin in Lewy body dementia patients. Axovant has stated plans to initiate a Phase 3 in the second half of 2017
- **Eisai**
 - On December 28, 2016, Arena and Eisai Co., Ltd. and Eisai Inc. (collectively, “Eisai”) amended and replaced the BELVIQ® (lorcaserin HCl) marketing and supply agreement. Under the revised agreements, Eisai acquired global commercialization rights to BELVIQ and is responsible for all lorcaserin development expenses going forward. The financial terms of the revised agreement are expected to provide Arena with \$23 million of cash payments, including \$10 million received in the fourth quarter, and over \$80 million of potential cost relief on lorcaserin development obligations in the next three years. In addition, Arena will continue to be eligible to receive royalty payments on net sales of BELVIQ and participate in the upside potential of lorcaserin from additional geographies and clinical trials such as the ongoing cardiovascular outcomes trial, CAMELLIA
 - As a result of the Eisai transaction, a significant amount of non-cash items were recognized in the 2016 financial statements

Financial Update

Fourth Quarter 2016 Financial Results

- Revenues totaled \$85.4 million, including \$15.2 million in net product sales of BELVIQ, \$1.3 million in milestone payments earned from Eisai and Ildong for BELVIQ, and \$66.1 million of revenue associated with upfront BELVIQ payments
 - Research and development expenses totaled \$11.9 million
 - General and administrative expenses totaled \$7.3 million
 - Impairment of assets totaled \$21.8 million
 - Net income was \$38.3 million or \$0.16 per share
-

Full Year 2016 Financial Results

- Revenues totaled \$124.0 million, including \$26.3 million in net product sales of BELVIQ, \$12.3 million of milestone payments earned from Eisai and Ildong for BELVIQ, and \$72.1 million of revenue associated with upfront BELVIQ payments
- Research and development expenses totaled \$66.4 million
- General and administrative expenses totaled \$31.2 million
- Restructuring charges totaled \$6.3 million
- Impairment of assets totaled \$21.8 million
- Net loss was \$22.9 million, or \$0.09 per share

At December 31, 2016, cash and cash equivalents totaled \$90.7 million and approximately 243 million shares of Arena common stock were outstanding.

2017 Financial Guidance

The Company expects the full year 2017 net cash used in operating and investing activities to be \$80 to \$100 million, assuming no additional partnerships and no adjustment to our development plans.

Conference Call & Webcast Information

The Company will host a conference call and live webcast with the investment community today, Tuesday, March 14, 2017, at 4:30 p.m. ET to discuss the financial results and provide a corporate update.

When: March 14, 2017, 4:30 p.m. ET

Dial-in: (877) 643-7155 (United States) or (914) 495-8552 (International)

Conference ID: 80816089

Please join the conference call at least 10 minutes early to register.

You can access the live webcast under the investor relations section of Arena's website at: www.arenapharm.com. A replay of the conference call will be archived under the investor relations section of Arena's website for 30 days shortly after the call.

About Arena Pharmaceuticals

Arena Pharmaceuticals is a biopharmaceutical company focused on developing novel, small molecule drugs with optimized receptor pharmacology designed to deliver broad clinical utility across multiple therapeutic areas. Our proprietary pipeline includes potentially first- or best-in-class programs for which we own global commercial rights. Our three most advanced investigational clinical programs are ralinepag (APD811) in Phase 2 evaluation for pulmonary arterial hypertension (PAH), etrasimod (APD334) in Phase 2 evaluation for multiple autoimmune indications, and APD371 entering Phase 2 evaluation for the treatment of pain associated with Crohn's disease. In addition, Arena has collaborations with the following pharmaceutical companies: Eisai Co., Ltd. and Eisai Inc. (commercial stage), Axovant Sciences (Phase 2 candidate), and Boehringer Ingelheim International GmbH (preclinical candidate).

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about expected results, data readouts and timing relating to ongoing clinical trials; expected payments and potential cost relief under the revised agreements with Eisai; financial guidance for 2017; and Arena's focus, goals, strategy and clinical programs. For such statements, Arena claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited

to, the following: the risk that we may need additional funds to advance all of our programs, and you and others may not agree with the manner we allocate our resources; risks related to developing and commercializing drugs; cash and revenues generated from BELVIQ and our revised agreements with Eisai; the risk that Arena's revenues are based in part on estimates, judgment and accounting policies, and incorrect estimates or disagreement regarding estimates or accounting policies may result in changes to Arena's guidance or previously reported results; the timing and outcome of research, development and regulatory review is uncertain, and our drug candidates may not advance in development or be approved for marketing; government and third-party payor actions, including relating to reimbursement and pricing; risks related to relying on collaborative arrangements; the entry into or modification or termination of collaborative arrangements; unexpected or unfavorable new data; nonclinical and clinical 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 before or after approval; Arena's and third parties' intellectual property rights; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; clinical trials and other studies may not proceed at the time or in the manner expected or at all; and satisfactory resolution of litigation or other disagreements with others. Additional factors that could cause actual results to differ materially from those stated or implied by Arena's forward-looking statements are disclosed in Arena's filings with the Securities and Exchange Commission. These forward-looking statements represent Arena's judgment as of the time of this release. Arena disclaims any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

Contact:

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(Tables Follow)

Arena Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)

	Three months ended		Year ended	
	December 31,		December 31,	
	2016	2015	2016	2015
	(unaudited)			
Revenues				
Net product sales	\$ 15,245	\$ 3,939	\$ 26,349	\$ 19,726
Other Eisai collaboration revenue	61,546	2,091	79,701	9,505
Other collaboration revenue	7,730	670	13,796	4,845
Toll manufacturing	853	1,051	4,129	4,250
Total revenues	<u>85,374</u>	<u>7,751</u>	<u>123,975</u>	<u>38,326</u>
Operating Costs & Expenses				
Cost of product sales	5,136	2,461	9,297	8,590
Cost of toll manufacturing	1,168	787	6,044	4,585
Research & development	11,911	20,170	66,425	88,411
General & administrative	7,264	9,655	31,243	35,966
Restructuring charges	0	3,972	6,346	3,972
Impairment of long-living assets	21,766	0	21,766	0
Total operating costs & expenses	<u>47,245</u>	<u>37,045</u>	<u>141,121</u>	<u>141,524</u>
Interest & Other Income (Expense)				
Interest income	43	53	290	158
Interest expense	(1,605)	(1,695)	(6,512)	(6,828)
Gain from valuation of derivative liabilities	0	0	0	474
Other	1,747	477	472	1,415
Total interest & other income (expense), net	<u>185</u>	<u>(1,165)</u>	<u>(5,750)</u>	<u>(4,781)</u>
Net income (loss)	<u>38,314</u>	<u>(30,459)</u>	<u>(22,896)</u>	<u>(107,979)</u>
Less net loss attributable to noncontrolling interest in consolidated variable interest entity	258	0	380	0
Net income (loss) attributable to stockholders of Arena	<u>\$ 38,572</u>	<u>\$ (30,459)</u>	<u>\$ (22,516)</u>	<u>\$ (107,979)</u>
Net income(loss) attributable to stockholders of Arena per share:				
Basic	<u>\$ 0.16</u>	<u>\$ (0.13)</u>	<u>\$ (0.09)</u>	<u>\$ (0.45)</u>
Diluted	<u>\$ 0.16</u>	<u>\$ (0.13)</u>	<u>\$ (0.09)</u>	<u>\$ (0.45)</u>
Shares used in calculating net loss attributable to stockholders of Arena per share:				
Basic	<u>243,325</u>	<u>242,566</u>	<u>243,133</u>	<u>240,671</u>
Diluted	<u>243,495</u>	<u>242,566</u>	<u>243,133</u>	<u>240,671</u>

Arena Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheet Data
(In thousands)

	December 31, 2016	December 31, 2015
	1	1
Assets		
Cash & cash equivalents	\$ 90,712	\$ 156,184
Accounts receivable	20,162	4,934
Inventory	6,708	9,502
Prepaid expenses & other current assets	2,307	4,218
Land, property & equipment, net	43,828	71,828
Intangibles & other non-current assets	5,293	10,126
Total assets	\$ 169,010	\$ 256,792
Liabilities & Equity		
Accounts payable & accrued liabilities	\$ 25,073	\$ 25,493
Total deferred revenues	37,455	109,042
Total lease financing obligations & other long-term liabilities	66,087	68,715
Total equity	40,395	53,542
Total liabilities & equity	\$ 169,010	\$ 256,792

¹ The Condensed Consolidated Balance Sheet Data has been derived from the audited financial statements as of that date.

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