

PDL BIOPHARMA, INC.

FORM 8-K (Current report filing)

Filed 06/05/17 for the Period Ending 06/05/17

Address	932 SOUTHWOOD BLVD INCLINE VILLAGE, NV 89451
Telephone	775-832-8500
CIK	0000882104
Symbol	PDLI
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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): June 5, 2017

PDL BioPharma, Inc.

(Exact name of Company as specified in its charter)

000-19756
(Commission File Number)

Delaware
(State or Other Jurisdiction of Incorporation)

94-3023969
(I.R.S. Employer Identification No.)

**932 Southwood Boulevard
Incline Village, Nevada 89451**
(Address of principal executive offices, with zip code)

(775) 832-8500
(Company's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Company under any of the following provisions:

- 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.

Item 8.01 Other Events

On June 5, 2017, PDL BioPharma, Inc. (the "Company") announced that its subsidiary, Noden Pharma DAC ("Noden"), received a Paragraph IV Notice Letter advising that Anchen Pharmaceuticals, Inc. ("Anchen") submitted an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration (the "FDA") seeking authorization from the FDA to manufacture and market a generic version of Tekturna[®] aliskiren hemifumarate tablets, 150 mg and 300 mg, in the United States.

The Notice Letter contains certifications against U.S. Patent No. 8,617,595, which is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for Tekturna as expiring on February 19, 2026.

Noden is aware that Novartis Pharmaceuticals Corporation ("Novartis") received Paragraph IV certifications from Par Pharmaceuticals, Inc. ("Par") for Tekturna HCT and Anchen on December 31, 2013. Novartis did not file a responsive patent infringement suit related to these certifications. However, to Noden's knowledge, neither Par nor Anchen have in the meantime commercialized generic aliskiren products.

Noden intends to vigorously defend its intellectual property rights related to Tekturna.

The press release is attached hereto as Exhibit 99.1, which is incorporated herein by reference.

Cautionary Statements

This filing, the press release and the Company's statements herein and in the attached press release contain "forward-looking" statements as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations or predictions of future conditions, events or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates," "projects," "forecasts," "may," "should," variations of such words and similar expressions are intended to identify such forward-looking statements. The forward-looking statements are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the statements. Forward-looking statements in this filing and in the attached press release should be evaluated together with the many uncertainties that affect the business of the Company and its markets, particularly those discussed in the risk factors and cautionary statements contained in the Company's annual report filed with the SEC on March 1, 2017, as well as subsequent filings. All forward-looking statements are expressly qualified in their entirety by such factors. The forward-looking statements are representative only as of the date they are made, and the Company assumes no responsibility to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release

SIGNATURES

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

PDL BIOPHARMA, INC.
(Company)

By: /s/ John P. McLaughlin
John P. McLaughlin
President, Chief Executive Officer

Dated: June 5, 2017

Exhibit Index

Exhibit No.	Description
99.1	Press Release

**Contacts:**

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Noden Pharma Notified of ANDA Filing for Tekturna[®]

INCLINE VILLAGE, NV, June 5, 2017 - PDL BioPharma, Inc. (PDL) (NASDAQ: PDLI) today announced that its subsidiary, Noden Pharma DAC (Noden), received a Paragraph IV Notice Letter advising that Anchen Pharmaceuticals, Inc. (Anchen) submitted an Abbreviated New Drug Application (“ANDA”) to the United States Food and Drug Administration (FDA) seeking authorization from the FDA to manufacture and market a generic version of Tekturna[®] aliskiren hemifumarate tablets, 150 mg and 300 mg, in the United States.

The Notice Letter contains certifications against U.S. Patent No. 8,617,595, which is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) for Tekturna as expiring on February 19, 2026.

Noden is aware that Novartis received Paragraph IV certifications from Par Pharmaceuticals, Inc. (Par) for Tekturna HCT and Anchen on December 31, 2013. Novartis did not file a responsive patent infringement suit related to these certifications. However, to Noden’s knowledge, neither Par nor Anchen have in the meantime commercialized generic aliskiren products.

Noden intends to vigorously defend its intellectual property rights related to Tekturna.

About Tekturna

Tekturna, also known as Rasilez outside the U.S., is a high blood pressure medication. It is the only product available in a class of high blood pressure drugs called “direct renin inhibitors,” which lowers blood pressure by blocking the enzyme renin.

About Noden Pharma

Noden Pharma DAC is a global specialty pharmaceutical company that is focused on acquiring prescription medicines across a broad range of therapeutic areas in international markets. The company focuses its resources on acquiring and optimizing established medicines. Corporate headquarters are located in Dublin, Ireland.

About PDL BioPharma

PDL seeks to provide a significant return for its shareholders by acquiring and managing a portfolio of companies, products, royalty agreements and debt facilities in the biotech, pharmaceutical and medical device industries. In late 2012, PDL began providing alternative sources of capital through royalty monetizations and debt facilities and in 2016, began making equity investments in commercial stage companies, the first being Noden Pharma DAC. PDL has committed over \$1.4 billion and funded approximately \$1.1 billion in these investments to date. PDL is headquartered in Incline Village, Nevada.

For more information, please visit www.pdl.com. PDL BioPharma and the PDL BioPharma logo are considered trademarks of PDL BioPharma, Inc.