INFINITY PHARMACEUTICALS, INC.
Form 8-K
September 03, 2014

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): September 2, 2014

Infinity Pharmaceuticals, Inc.

(Exact name of registrant as specified in charter)

Delaware	**000-31141**	**33-0655706**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

780 Memorial Drive, Cambridge, MA **02139**
(Address of principal executive offices) **(Zip Code)**
Registrant s telephone number, including area code: (617) 453-1000

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:

¨ 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))

Item 1.01 Entry into a Material Definitive Agreement

Collaboration and License Agreement

On September 2, 2014, Infinity Pharmaceuticals, Inc. (we , us or our) entered into a collaboration and license agreement with AbbVie Inc., or AbbVie, which we refer to as the AbbVie agreement. Under the AbbVie agreement, we will collaborate with AbbVie to develop and commercialize products containing the compound known as duvelisib (also known as IPI-145), or duvelisib products, in oncology indications. We licensed rights to duvelisib, an oral inhibitor of phosphoinositide-3-kinase, or PI3K, delta,gamma, from Intellikine LLC.

Licensed Rights

Under the terms of the AbbVie agreement, we have granted to AbbVie licenses under applicable patents, patent applications, know-how and trademarks to develop, commercialize and manufacture duvelisib products in oncology indications. These licenses are generally co-exclusive with rights we retain, except that we have granted AbbVie exclusive licenses to commercialize duvelisib products outside the United States. We and AbbVie retain the rights to perform our respective obligations and exercise our respective rights under the AbbVie agreement, and we and AbbVie may each grant sublicenses to affiliates or third parties.

Development, Commercialization and Manufacturing Responsibilities

Under the AbbVie agreement, we and AbbVie have created a governance structure, including committees and working groups to manage the development, manufacturing and commercialization responsibilities for the duvelisib products. Generally, we and AbbVie must mutually agree on decisions, although in specified circumstances either we or AbbVie would be able to break a deadlock.

We have primary responsibility for the conduct of development of duvelisib products, except that AbbVie has responsibility for the conduct of certain contemplated combination clinical studies, which we refer to as the AbbVie studies. Excluding the AbbVie studies, to the extent they occur, the costs of which would be shared equally, we are responsible for all costs to develop duvelisib products up to a maximum amount of $667,000,000, after which we will share duvelisib product development costs equally with AbbVie. We and AbbVie share oversight of development and have each agreed to use diligent efforts, as defined in the AbbVie agreement, to carry out our development activities under an agreed upon development plan.

We and AbbVie share operational responsibility and decision making authority for commercialization of duvelisib products in the United States. Specifically, we have the primary responsibility for advertising, distribution, and booking sales, and we share certain other commercialization functions with AbbVie. We and AbbVie will each provide half of the sales representative effort to promote duvelisib products in the United States. Outside the United States, AbbVie has, with limited exceptions, operational responsibility and decision making authority to commercialize duvelisib products.

We have the responsibility to manufacture products containing duvelisib under the AbbVie agreement until we transition the manufacturing to AbbVie, which we expect to occur as promptly as practicable while ensuring continuity of supply. We and AbbVie will equally share the manufacturing or supply costs for duvelisib products for clinical studies and for commercialization in the United States. AbbVie will bear the cost of manufacturing duvelisib products for commercialization outside of the United States.

Financial Terms

AbbVie has agreed to pay us a non-creditable $275,000,000 upfront payment within 45 days. AbbVie has also agreed to pay us milestone payments associated with specified development, regulatory and commercialization events, up to

an aggregate of $530,000,000 if all the milestones are achieved. Under the terms of the AbbVie agreement, we and AbbVie will equally share commercial profits or losses of duvelisib products in the United States.

Outside the United States, AbbVie has agreed to pay us a tiered royalty on net sales ranging from 23.5% to 30.5%, depending on annual net sales by AbbVie, its affiliates and its sublicensees. This tiered royalty can be reduced based on specified factors, including patent expiry, generic entry, reduction in our

royalties to Mundipharma International Corporation Limited and Purdue Pharmaceuticals Products L.P. and royalties paid to third parties with blocking intellectual property. These royalties are payable on a product-by-product and country-by-country basis until AbbVie ceases selling the product in the country.

Exclusivity

Subject to limited exceptions, we have agreed that we and our affiliates will not commercialize, or assist others in commercializing, in oncology indications any product that is a PI3K delta,gamma dual inhibitor that meets certain agreed-to criteria, other than the duvelisib products, and AbbVie has agreed to similar restrictions. Registration directed clinical trials and commercialization of duvelisib products for uses outside of oncology indications would require our and AbbVie s mutual consent.

Term and Termination

The AbbVie agreement will remain in effect until all development, manufacturing and commercialization of duvelisib products cease, unless terminated earlier. Either we or AbbVie may terminate the AbbVie agreement if the other party is subject to certain insolvency proceedings or if the other party materially breaches the AbbVie agreement and the breach remains uncured for a specified period, which may be extended in certain circumstances. However, we may terminate the AbbVie agreement only on a country by country basis in the event AbbVie is not using diligent efforts to obtain regulatory approval or to commercialize duvelisib products in a country outside the United States. AbbVie may also terminate the AbbVie agreement for convenience after a specified notice period. In the event there is a material uncured breach by either us or AbbVie of development or commercialization obligations, the non-breaching party may also have the right to assume and conduct such applicable development or commercialization obligations. If AbbVie or any of its affiliates or sublicensees challenges the patents we have licensed to AbbVie, we can terminate the AbbVie agreement if the challenge is not withdrawn after a specified notice period.

If the AbbVie agreement is terminated, we would receive all rights to the regulatory filings related to duvelisib upon our request, our license to AbbVie terminates, and AbbVie grants us a perpetual, irrevocable license to develop, manufacture and commercialize products containing duvelisib, excluding any compound which is covered by patent rights controlled by AbbVie or its affiliates. This license would be royalty free, unless the AbbVie agreement is terminated for material breach, in which case, depending on the breaching party and the timing of the material breach, a royalty rate may be payable by us ranging from a low single-digit percentage to a low double-digit percentage of net sales, and, in some cases, subject to a payment cap.

If the AbbVie agreement is terminated, there are certain wind down obligations to ensure a smooth transition of the responsibilities of the parties.

The foregoing description of the collaboration and license agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the AbbVie agreement, which we intend to file with the Securities and Exchange Commission as an exhibit to our Quarterly Report on Form 10-Q for the period ending September 30, 2014.

Item 8.01 Other Events

On September 3, 2014, we issued a press release announcing the entry into a collaboration and license agreement with AbbVie Inc. A copy of this press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) The following exhibit is included in this report:

Exhibit No.	Description
99.1	Press Release dated September 3, 2014

SIGNATURE

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 hereunto duly authorized.

INFINITY PHARMACEUTICALS, INC.

Date: September 3, 2014

By: /s/ Adelene Q. Perkins
Adelene Q. Perkins
President & Chief Executive Officer