

SYNDAX PHARMACEUTICALS INC

FORM 8-K (Current report filing)

Filed 10/17/17 for the Period Ending 10/13/17

Address	35 GATEHOUSE DRIVE BUILDING D, FLOOR 3 WALTHAM, MA, 02451
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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): October 13, 2017

SYNDAX PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(state or other jurisdiction
of incorporation)

001-37708
(Commission
File Number)

32-0162505
(I.R.S. Employer
Identification No.)

Building D, Floor 3
35 Gatehouse Drive
Waltham, Massachusetts
(Address of principal executive offices)

02451
(Zip Code)

Registrant's telephone number, including area code: (781) 419-1400

(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 Instruction 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 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 1.01. Entry into a Material Definitive Agreement.

On October 13, 2017, Syndax Pharmaceuticals, Inc. (the “Company”) entered into a license agreement (the “Agreement”) with Vitae Pharmaceuticals, Inc. (“Allergan”), a subsidiary of Allergan plc, under which Allergan granted to the Company a worldwide, sublicenseable, exclusive license to a portfolio of preclinical, orally-available small molecule inhibitors of the interaction of Menin with the Mixed Lineage Leukemia (“MLL”) protein (the “Menin Assets”).

Pursuant to the Agreement, the Company will make an upfront payment of \$5.0 million to Allergan, and, subject to the achievement of certain milestone events, the Company may be required to pay Allergan up to \$99 million in one-time development and regulatory milestone payments over the term of the Agreement. In the event that the Company or any of its affiliates or sublicensees commercializes the Menin Assets, the Company will also be obligated to pay Allergan low single to low double-digit royalties on sales, subject to reduction in certain circumstances, as well as up to an aggregate of \$70 million in potential one-time sales-based milestone payments based on achievement of certain annual sales thresholds. Under certain circumstances, the Company may be required to share a percentage of non-royalty income from sublicensees, subject to certain deductions, with Allergan. The Company will be solely responsible for the development and commercialization of the Menin Assets.

Each party may terminate the agreement for the other party’s uncured material breach or insolvency, and the Company may terminate the agreement at will at any time upon advance written notice to Allergan. Allergan may terminate the agreement if the Company or any of its affiliates or sublicensees institutes a legal challenge to the validity, enforceability or patentability of the licensed patent rights. Unless terminated earlier in accordance with its terms, the agreement will continue on a country-by-country and product-by-product basis until the later of: (i) the expiration of all of the licensed patent rights in such country; (ii) the expiration of all regulatory exclusivity applicable to the product in such country; and (iii) 10 years from the date of the first commercial sale of the product in such country.

The foregoing description of the Agreement is only a summary and is qualified in its entirety by reference to the Agreement, a copy of which will be filed as an exhibit to the Company’s Annual Report on Form 10-K for the year ended December 31, 2017.

A copy of the press release issued in connection with the Company’s announcement of the Agreement on October 17, 2017 is attached hereto as Exhibit 99.1.

Cautionary Note on Forward-Looking Statements

This Current Report on Form 8-K (the “Current Report”) contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “may,” “will,” “expect,” “plan,” “anticipate,” “estimate,” “intend,” “believe” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on the Company’s expectations and assumptions as of the date of this Current Report. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this Current Report include, but are not limited to, the Company’s potential payment of upfront and milestone payments and royalties. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of

the Company's collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. Other factors that may cause the Company's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in the Company's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, the Company assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Item 8.01. Other Events.

Common Stock Registered Direct Offering

On October 17, 2017, the Company issued a press release entitled "Syndax Announces \$25 Million Registered Direct Offering of Common Stock." A copy of the press release issued in connection with the offering is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Supplemental Risk Factors

In connection with disclosures made in connection with the registered direct offering referenced above (which such disclosures are also included in a prospectus supplement to the base prospectus included in the Company's shelf registration statement on Form S-3 (File No. 333-217172)), the Company is filing the risk factor attached hereto as Exhibit 99.3 for the purpose of supplementing the risk factor disclosure contained in its most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 filed with the Securities and Exchange Commission on August 10, 2017. The supplemental risk factor attached as Exhibit 99.3 hereto is incorporated herein by reference. The supplemental risk factor should be carefully considered along with any other risk factors related to the Company's business identified in the Company's other periodic and current reports filed with the Securities and Exchange Commission. The occurrence of any one or more of these risks could materially and adversely affect the Company's business, financial condition and results of operations.

This Current Report on Form 8-K does not constitute an offer to sell, or a solicitation of an offer to buy, any securities of the Company.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated October 17, 2017
99.2	Press Release, dated October 17, 2017
99.3	Supplemental Risk Factor Disclosure

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 hereunto duly authorized.

SYNDAX PHARMACEUTICALS, INC.

By: /s/ Briggs W. Morrison, M.D.

Briggs W. Morrison, M.D.
Chief Executive Officer

Dated: October 17, 2017



Syndax Expands Pipeline with Exclusive Worldwide License to Allergan's Portfolio of Menin-MLL Inhibitors

– Compounds Provide Novel Therapeutic Approach for the Potential Treatment of Defined Genetic Subtype of Pediatric and Adult Acute Leukemias –

WALTHAM, Mass., October 17, 2017 (PRNEWSWIRE) — Syndax Pharmaceuticals, Inc. (“Syndax,” the “Company” or “we”) (Nasdaq:SNDX), a clinical stage biopharmaceutical company developing entinostat and SNDX-6352 in multiple cancer indications, today announced that it has entered into an exclusive worldwide license agreement with Vitae Pharmaceuticals, Inc., a subsidiary of Allergan plc, for a portfolio of preclinical, orally-available small molecule inhibitors of the interaction of Menin with the Mixed Lineage Leukemia (“MLL”) protein. These compounds have potential application in the treatment of a genetically-defined subset of acute leukemias with chromosomal rearrangements in the MLL gene (“MLL-r”). Syndax expects to initiate clinical studies in 2019.

“This agreement represents another strategic addition to our pipeline that we believe will enhance the long-term value of Syndax,” said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. “Syndax is well positioned to develop this unique product portfolio which holds the potential to significantly change the treatment paradigm for acute leukemic patients harboring MLL translocations, a disease that may meet the guidelines for orphan designation.”

“The Menin-MLL-r interaction is thought to play a central role in the pathology of acute leukemia patients with MLL translocations, a patient population routinely identified in clinical practice today,” said Michael L. Meyers, M.D., Ph.D., Chief Medical Officer of Syndax. “While intensive chemotherapy regimens are often employed in these patients, the 5-year survival rate remains significantly below 50% due to the lack of effective treatment options. We believe that this portfolio of compounds holds the potential to serve as an effective oral therapeutic option for pediatric and adult patients with MLL-r-driven leukemias.”

Under the terms of the license agreement, Syndax will make a one-time upfront payment to Allergan and will be responsible for development, manufacturing and global commercialization of the portfolio. Allergan will receive development and commercial stage milestones and tiered royalties on net sales of commercialized products.

About MLL Rearranged (MLL-r) Leukemias

Rearrangements of the MLL gene occur in 70-80% of infant acute leukemias and up to 10% of adult acute leukemias and are associated with a poor prognosis, with less than 40% of infants with MLL-r surviving past 5 years. The protein products of MLL gene rearrangements require interaction with a protein called Menin in order to drive leukemic cancer growth. Disruption of the Menin-MLL-r interaction has been shown to halt the growth of MLL-r leukemic cells. MLL-r leukemias are routinely diagnosed through currently available genetic screening techniques in leukemic cells, but there are currently no approved therapies indicated for MLL-r leukemias.



About Syndax Pharmaceuticals, Inc.

Syndax is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. Our lead product candidate, entinostat, which was granted Breakthrough Therapy designation by the FDA following positive results from our Phase 2b clinical trial, ENCORE 301, is currently being evaluated in a Phase 3 clinical trial in combination with exemestane for advanced hormone receptor positive, human epidermal growth factor receptor 2 negative breast cancer. Given its potential ability to block the function of immune suppressive cells in the tumor microenvironment, entinostat is also being evaluated in combination with approved PD-1 antagonists. Ongoing Phase 1b/2 clinical trials combine entinostat with KEYTRUDA from Merck & Co., Inc. for non-small cell lung cancer, melanoma and colorectal cancer; with TECENTRIQ® from Genentech, Inc. for triple negative breast cancer; and with BAVENCIO® from Pfizer Inc. and Merck KGaA, Darmstadt, Germany, for ovarian cancer. Our second product candidate, SNDX-6352, is a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor and may also block the function of immune suppressive cells in the tumor microenvironment. SNDX-6352 is being evaluated in a Phase 1 clinical trial and is expected to be developed to treat a variety of cancers.

Syndax's Cautionary Note on Forward-Looking Statements

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SNDX-G



Syndax Announces \$25 Million Registered Direct Offering of Common Stock

WALTHAM, Mass., October 17, 2017 (PRNEWSWIRE) — Syndax Pharmaceuticals, Inc. (“Syndax,” the “Company” or “we”) (Nasdaq:SNDX), a clinical stage biopharmaceutical company developing entinostat and SNDX-6352 in multiple cancer indications, today announced that it has agreed to sell 2,021,018 shares of its common stock to Biotechnology Value Fund, L.P. and certain of its affiliates (“BVF”) in a registered direct offering. Syndax anticipates aggregate gross proceeds from the offering will be approximately \$25.0 million based on the offering price of \$12.37 per share, representing the closing price of the Company’s shares on the Nasdaq Global Select Market on Friday, October 13, 2017. The closing of the transaction is subject to customary closing conditions. BTIG, LLC served as a capital markets advisor for the Company in connection with the offering.

The shares described above are being offered by Syndax pursuant to a shelf registration statement previously filed with the Securities and Exchange Commission (the “SEC”), which the SEC declared effective on April 20, 2017. A final prospectus supplement related to the offering will be filed with the SEC, and will be available on the SEC’s website located at <http://www.sec.gov>.

This press release does not constitute an offer to sell or the solicitation of an offer to buy the securities, nor shall there be any sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such state. Any offering of the securities under the resale registration statement will only be by means of a prospectus.

About Syndax Pharmaceuticals, Inc.

Syndax is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. Our lead product candidate, entinostat, which was granted Breakthrough Therapy designation by the FDA following positive results from our Phase 2b clinical trial, ENCORE 301, is currently being evaluated in a Phase 3 clinical trial in combination with exemestane for advanced hormone receptor positive, human epidermal growth factor receptor 2 negative breast cancer. Given its potential ability to block the function of immune suppressive cells in the tumor microenvironment, entinostat is also being evaluated in combination with approved PD-1 antagonists. Ongoing Phase 1b/2 clinical trials combine entinostat with KEYTRUDA from Merck & Co., Inc. for non-small cell lung cancer, melanoma and colorectal cancer; with TECENTRIQ® from Genentech, Inc. for triple negative breast cancer; and with BAVENCIO® from Pfizer Inc. and Merck KGaA, Darmstadt, Germany, for ovarian cancer. Our second product candidate, SNDX-6352, is a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor and may also block the function of immune suppressive cells in the tumor microenvironment. SNDX-6352 is being evaluated in a Phase 1 clinical trial and is expected to be developed to treat a variety of cancers.



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SNDX-G

Risks Related to Intellectual Property

If we breach the Allergan license agreement related to the Menin Assets or if the Allergan license agreement is otherwise terminated, we could lose the ability to continue the development and commercialization of the Menin Assets.

Our commercial success depends upon our ability to develop, manufacture, market and sell one or more of the Menin Assets. Subject to the achievement of certain milestone events, we may be required to pay Allergan up to \$99 million in one-time development and regulatory milestone payments over the term of the Allergan license agreement. In the event that we or any of our affiliates or sublicensees commercializes any of the Menin Assets, we will also be obligated to pay Allergan low single to low double-digit royalties on sales, subject to reduction in certain circumstances, as well as up to an aggregate of \$70 million in potential one-time sales-based milestone payments based on achievement of certain annual sales thresholds. Under certain circumstances, we may be required to share a percentage of non-royalty income from sublicensees, subject to certain deductions, with Allergan.

Either party may terminate the Allergan license agreement in its entirety or with respect to certain countries in the event of an uncured material breach by the other party. Either party may terminate the Allergan license agreement if voluntary or involuntary bankruptcy proceedings are instituted against the other party, if the other party makes an assignment for the benefit of creditors, or upon the occurrence of other specific events relating to the insolvency or dissolution of the other party. Allergan may terminate the Allergan license agreement if we seek to revoke or challenge the validity of any patent licensed to us by Allergan under the Allergan license agreement or if we procure or assist a third party to take any such action.

Unless terminated earlier in accordance with its terms, the Allergan license agreement will continue on a country-by-country and product-by-product basis until the later of: (i) the expiration of all of the licensed patent rights in such country; (ii) the expiration of all regulatory exclusivity applicable to the product in such country; and (iii) 10 years from the date of the first commercial sale of the product in such country. We cannot determine the date on which our royalty payment obligations to Allergan would expire because no commercial sales of the Menin Assets have occurred and the last-to-expire relevant patent covering the Menin Assets in a given country may change in the future.

If the Allergan license agreement is terminated, we would not be able to develop, manufacture, market or sell any of the Menin Assets and would need to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all.