# 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): **April 25, 2019**

# Stemline Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

| **Delaware** | **001-35619** | **45-0522567** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**750 Lexington Avenue**
**Eleventh Floor**
**New York, New York 10022**
(Address of Principal Executive Offices)

**(646) 502-2311**
(Registrant'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 registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act.

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act.

☐ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.

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

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 April 25, 2019, Stemline Therapeutics, Inc. announced that the pivotal trial results of ELZONRIS™ (tagraxofusp), a targeted therapy directed to CD123, in patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) have been published in the April 25, 2019 issue of the *New England Journal of Medicine*.

ELZONRIS is approved by the U.S. Food and Drug Administration (FDA) for the treatment of BPDCN in adults and pediatric patients two years and older, and is commercially available in the U.S.

A copy 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.

The following exhibit is furnished herewith:

| Exhibit Number | Description |
|---|---|
| 99.1 | Press release issued by Stemline Therapeutics, Inc., dated April 25, 2019, announcing *New England Journal of Medicine* Publication of ELZONRIS (tagraxofusp) Pivotal Study Results . |

**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.

Date: April 29, 2019

**Stemline Therapeutics, Inc.**
(Registrant)

By /s/ Kenneth Hoberman
Kenneth Hoberman
Chief Operating Officer

**Exhibit 99.1**

**Stemline Therapeutics Announces *New England Journal of Medicine* Publication of ELZONRIS (tagraxofusp) Pivotal Study Results**

NEW YORK, April 25, 2019 (GLOBE NEWSWIRE) — Stemline Therapeutics, Inc. (Nasdaq: STML), a commercial-stage biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics, announced today that the pivotal trial results of ELZONRIS™ (tagraxofusp), a targeted therapy directed to CD123, in patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) have been published in the April 25 issue of the *New England Journal of Medicine*.

ELZONRIS (tagraxofusp-erzs) is approved by the U.S. Food and Drug Administration (FDA) for the treatment of BPDCN in adults and pediatric patients two years and older, and is commercially available in the U.S.

Andrew Lane, M.D., Ph.D., Assistant Professor at Harvard Medical School and Dana-Farber Cancer Institute and a co-lead author of the manuscript, offered: "This publication by the *New England Journal of Medicine* highlights the increasing recognition of BPDCN in the medical community. As this landmark paper lays out, treatment with tagraxofusp resulted in a high remission rate while maintaining a predictable and a manageable safety profile, providing data supporting the first-ever approved agent for treatment of this aggressive malignancy. We thank our patients and collaborators for the years of research that have led to a new era in the therapy of BPDCN."

Ivan Bergstein, M.D., Chief Executive Officer of Stemline, commented "The publication of these pivotal data in the *New England Journal of Medicine* underscores both the clinical benefit of ELZONRIS for patients with BPDCN as well as the growing worldwide awareness of this serious hematologic malignancy. We are very thankful to the patients, their families, and the investigators who helped make this breakthrough product a reality."

**About ELZONRIS™**

ELZONRIS (tagraxofusp-erzs), a CD123-directed cytotoxin, is approved by the U.S. Food and Drug Administration (FDA) and commercially available in the U.S. for the treatment of adult and pediatric patients, two years or older, with blastic plasmacytoid dendritic cell neoplasm (BPDCN). For full prescribing information in the U.S., visit www.ELZONRIS.com. In Europe, a marketing authorization application (MMA) is under review by the European Medicines Agency (EMA). ELZONRIS is also being evaluated in additional clinical trials in other indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF) and acute myeloid leukemia (AML).

**About BPDCN**

BPDCN is an aggressive hematologic malignancy with historically poor outcomes and an area of unmet medical need. BPDCN typically presents in the bone marrow and/or skin and may also involve lymph nodes and viscera. The BPDCN cell of origin is the plasmacytoid dendritic cell (pDC) precursor. The diagnosis of BPDCN is based on the immunophenotypic diagnostic triad of CD123, CD4, and CD56, as well as other markers. For more information, please visit the BPDCN disease awareness website at www.bpdcninfo.com.

**About CD123**

CD123 is a cell surface target expressed on a wide range of myeloid tumors including blastic plasmacytoid dendritic cell neoplasm (BPDCN), certain myeloproliferative neoplasms (MPNs) including chronic myelomonocytic leukemia (CMML) and myelofibrosis (MF), acute myeloid leukemia (AML) (and potentially enriched in certain AML subsets), myelodysplastic syndrome (MDS), and chronic myeloid leukemia (CML). CD123 has also been reported on certain lymphoid malignancies including multiple

myeloma (MM), acute lymphoid leukemia (ALL), hairy cell leukemia (HCL), Hodgkin's lymphoma (HL), and certain Non-Hodgkin's lymphomas (NHL). In addition, CD123 has been detected on some solid tumors as well as autoimmune disorders including cutaneous lupus and scleroderma.

**About Stemline Therapeutics**

Stemline Therapeutics, Inc. is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics. ELZONRIS™ (tagraxofusp), a targeted therapy directed to CD123, is FDA-approved and commercially available in the U.S. for the treatment of adult and pediatric patients, two years or older, with blastic plasmacytoid dendritic cell neoplasm (BPDCN). In Europe, a marketing authorization application (MMA) is under review by the European Medicines Agency (EMA). ELZONRIS is also being evaluated in clinical trials in additional indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF) and acute myeloid leukemia (AML). Additional pipeline candidates include: SL-701 (immunotherapeutic; Phase 2 in glioblastoma patients completed), SL-801 (XPO1 inhibitor; Phase 1 in advanced solid tumor patients ongoing), SL-901 (novel kinase inhibitor; prior abbreviated European Phase 1, IND-enabling studies ongoing), and SL-1001 (novel RET kinase inhibitor, IND-enabling studies pending). For more information, please visit the company's website at www.stemline.com.

**Forward-Looking Statements**

Some of the statements included in this press release may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The factors that could cause our actual results to differ materially include: the success of our MAA submission to the EMA; the success and timing of our clinical trials and preclinical studies for our product candidates, including site initiation, institutional review board approval, scientific review committee approval, patient accrual, safety, tolerability and efficacy data observed, and input from regulatory authorities including the risk that the FDA, EMA, or other ex-U.S. national drug authority ultimately does not agree with our data, find our data supportive of approval, or approve any of our product candidates; the possibility that results of clinical trials are not predictive of safety and efficacy results of our product candidates in broader patient populations or of our products if approved; our plans to develop and commercialize our product candidates, including, but not limited to delays in arranging satisfactory manufacturing capabilities and establishing commercial infrastructure for ELZONRIS; product efficacy or safety concerns resulting in product recalls or regulatory action; the risk that estimates regarding the number of patients with the diseases that our products and product candidates may treat are inaccurate; inadequate market penetration of our products; our products not gaining acceptance among patients (and providers or third party payers) for certain indications (due to cost or otherwise); the risk that third party payors (including governmental agencies) will not reimburse for the use of ELZONRIS at acceptable rates or at all; the company's ability to produce, maintain or increase sales of ELZONRIS; the company's ability to develop and/or commercialize ELZONRIS; the adequacy of our pharmacovigilance and drug safety reporting processes; our available cash and investments; our ability to obtain and maintain intellectual property protection for our products and product candidates; delays, interruptions, or failures in the manufacture and supply of our products and product candidates; the performance of third-party businesses, including, but not limited to, manufacturers, clinical research organizations, clinical trial sponsors and clinical trial investigators; and other risk factors identified from time to time in our reports filed with the SEC. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof.

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