Clovis Oncology, Inc.
Form 8-K
November 19, 2013

**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): November 19, 2013**

**Clovis Oncology, Inc.**

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-35347** | **90-0475355** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

**2525 28th Street, Suite 100**

**Boulder, Colorado** **80301**
**(Address of principal executive offices)** **(Zip Code)**
**Registrant s telephone number, including area code: (303) 625-5000**

**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:

¨ 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))

On November 19, 2013, we acquired all of the issued and outstanding capital stock of EOS (Ethical Oncology Science) S.p.A., an Italian corporation ( EOS ), and thereby gained rights to develop and commercialize in the U.S. and Japan a compound known as lucitanib, an oral, potent, selective inhibitor of the tyrosine kinase activity of fibroblast growth factor receptors 1 and 2 and vascular endothelial growth factor receptors 1 through 3. In addition, we gained the rights to any future consideration due to EOS under the terms of an agreement whereby EOS sublicensed development and commercialization rights for lucitanib to Les Laboratoires Servier and Institut de Recherches Internationales Servier ( Servier ) in territories outside the U.S., Japan, and China.

**Item 1.01 Entry Into a Material Definitive Agreement.**

**Item 2.01 Completion of Acquisition or Disposition of Assets.**

Stock Purchase Agreement

On November 19, 2013, Clovis Oncology, Inc. (the Company or Clovis ) acquired (the Acquisition ) all of the issued and outstanding capital stock of EOS pursuant to the terms set forth in that certain Stock Purchase Agreement, dated as of November 19, 2013 (the Stock Purchase Agreement ), by and among the Company, EOS, its shareholders (the Sellers ) and Sofinnova Capital V FCPR, acting in its capacity as the Sellers representative. Following the Acquisition, EOS became a wholly-owned subsidiary of the Company. Under the terms of the Stock Purchase Agreement, the Company paid a purchase price comprised of $10,000,000 in cash and 3,713,731 shares of the Company s common stock, par value $.001 per share ( Company Common Stock ), subject to customary adjustments for working capital acquired in the Acquisition. In addition, pursuant to the Stock Purchase Agreement, the Company will also be obligated to pay to the Sellers certain milestone payments upon the successful development and commercialization by the Company and Servier of lucitanib. Specifically, the Company is obligated to pay Sellers (i) a milestone payment of $65,000,000 upon obtaining the first New Drug Application approval from the U.S. Food and Drug Administration with respect to lucitanib, (ii) a milestone payment of 15,000,000 upon receipt of a milestone payment from Servier pursuant to the Servier Agreement (as defined below) associated with the Marketing Authorization Application filing with the European Medicines Agency for the first indication of lucitanib, (iii) a milestone payment of 45,000,000 upon receipt of a milestone payment from Servier pursuant to the Servier Agreement associated with approval by the European Commission of the first Marketing Authorization for the first indication of lucitanib, and (iv) a milestone payment of 55,000,000 upon the receipt of a milestone payment from Servier pursuant to the Servier Agreement associated with the aggregate net sales of the development compound reaching a specified threshold in any four consecutive calendar quarters. The Stock Purchase Agreement includes customary representations, warranties, covenants and indemnities.

The foregoing description of the Stock Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the Stock Purchase Agreement, which is filed as Exhibit 2.1 hereto and is incorporated herein by reference. The representations and warranties contained in the Stock Purchase Agreement were made only for the purposes of the Stock Purchase Agreement and solely for the benefit of the parties thereto. Those representations and warranties may be subject to important limitations and qualifications agreed to by the contracting parties. Some of those representations and warranties may not be accurate or complete as of any particular date because they are subject to contractual standards of materiality different from that generally applicable to public disclosures to stockholders. Furthermore, the representations and warranties may have been made for the purposes of allocating contractual risk between the parties to such contract or other document instead of establishing these matters as facts, and they may or may not have been accurate as of any specific date and do not purport to be accurate as of the date of this Current Report on Form 8-K. Accordingly, you should not rely upon the representations and warranties in the Stock Purchase Agreement as statements of factual information.

Registration Rights Agreement

In connection with the Acquisition, the Sellers and the Company entered into a Registration Rights Agreement, dated as of November 19, 2013 (the Registration Rights Agreement ), pursuant to which the Company granted registration rights to the Sellers concerning the resale of the shares of Company Common Stock issued to the Sellers pursuant to the Stock Purchase Agreement. The Registration Rights Agreement requires the Company to, promptly following the Acquisition, file a resale registration statement covering the resale of the shares of Company Common Stock issued to the Sellers pursuant to the terms of the Stock Purchase Agreement and help facilitate one underwritten offering for the account of the Sellers. The Company is obligated to use commercially reasonable efforts to keep the registration statement effective as long as the Sellers hold registrable securities.

The foregoing description of the Registration Rights Agreement does not purport to be complete and is qualified in its entirety by reference to the Registration Rights Agreement, which is filed as Exhibit 4.1 hereto and is incorporated herein by reference.

Acquisition of EOS

This Current Report on Form 8-K provides the historical financial statements of EOS and its subsidiaries required under Item 9.01(a) and the pro forma financial information required under Item 9.01(b), and an overview of EOS business, which consists of the right to develop and commercialize lucitanib, is set forth below.

**EOS (Ethical Oncology Science) S.p.A.**

***Lucitanib a FGFR and VEGFR Inhibitor***

*Overview*

Lucitanib, also known as E-3810/S 80881, is an oral, potent, dual-selective inhibitor of the tyrosine kinase activity of fibroblast growth factor receptors 1 and 2 (FGFR1/2) and vascular endothelial growth factor (VEGF) receptors 1 through 3 (VEGFR1-3). EOS has in-licensed exclusive development and commercial rights to lucitanib on a global basis, excluding China, from Advenchen Laboratories LLC, a small pharmaceutical company focusing on pharmaceutical research and development involving small molecule cancer drug discovery programs. EOS, in turn, sublicensed lucitanib rights to markets outside of the U.S. and Japan to Servier. We intend to collaborate with Servier on the clinical development of lucitanib.

In a Phase I/IIa clinical study, lucitanib demonstrated multiple objective responses in FGFR1 gene-amplified breast cancer patients, and objective responses were also observed in patients with tumors often sensitive to VEGFR inhibitors, such as renal cell and thyroid cancer. FGFR amplification is common in a number of tumor types, including breast cancer and non-small cell lung cancer, and we intend to study lucitanib in these cancers as well as other solid tumors exhibiting FGFR pathway activation.

*FGF and VEGF*

Fibroblast growth factors (FGFs) are involved in cancer cell proliferation and new blood vessel formation. FGFs are a family of related extracellular proteins that normally regulate cell proliferation and survival in humans. They act by binding to and activating FGF receptors, or FGFRs, which are cell surface proteins that transmit growth signals to cells. Certain FGFs promote growth of multiple solid tumors by binding and activating FGFRs.

The FGF family consists of 22 known proteins called ligands that exert their physiological effect on cells by binding to four FGFRs (FGFR1, 2, 3 and 4). Some tumors contain an excessive number of FGFR1 gene copies, generated by a process called gene amplification. Amplification of the FGFR1 gene results in excess production, or the over-expression, of FGFR1 protein on the surface of the tumor cell. The over-expression of FGFR1 on the tumor cell surface leads to an increased binding of FGF ligands, which stimulate uncontrolled proliferation of some types of tumor cells.

In addition to FGFR1 gene amplification, certain tumors contain an excessive number of gene copies encoding FGF ligands 3, 4, and 19. Because these genes are located together on chromosome 11, amplification of FGF 3, 4, and 19 is commonly referred to as 11q amplification. The amplification of these genes in the tumor cell has the potential to increase FGFR activation and tumor growth.

Tumors with a relatively high incidence of FGFR1 and/or 11q gene amplification include breast cancer (10-24%), squamous non-small cell lung cancer (NSCLC) (17-34%), and head and neck cancers (9-35%). In addition, FGFR1/2 gene amplification/mutation is also observed at a frequency of 3-19% in a wide range of cancer indications including sarcoma, ovarian cancer, adenocarcinoma of the lung, bladder cancer, colorectal cancer and endometrial cancer.

The FGFR signaling pathway can also be activated in tumors by the mutation of genes encoding the FGF receptors. FGFR gene mutation alters the structure of the FGF receptor on the cell surface in such a manner as to trigger FGFR signaling in the absence of ligand binding, thereby stimulating uncontrolled cancer cell growth. In addition, some FGFs can promote tumor growth through the formation of new blood vessels in tumors in a process known as angiogenesis.

In concert with FGFs, VEGFs are also involved in the formation of new blood vessels in tumors. The VEGFs are a family of related extracellular proteins that normally regulate blood and lymphatic vessel development in humans. They act by binding to and activating VEGF receptors, which are cell surface proteins that transmit growth signals to specific cells that are involved in the development of new blood vessels. Certain VEGFs promote growth of multiple solid tumors by stimulating the formation of new blood vessels to feed the tumor and allow it to grow and metastasize. Tumors produce an excessive amount of VEGF. This results in excess VEGFR signaling and the formation of new blood vessels within the tumor. By triggering angiogenesis, cancerous cells can fuel their metabolic needs and direct their own uncontrolled cell division. The FGF and VEGF ligands that cause angiogenesis are often present in a wide range of cancer indications, including a type of kidney cancer called renal cell carcinoma, a type of liver cancer called hepatocellular carcinoma, head and neck cancers, and other solid tumors.

Considering the role of FGFR1/2 and VEGFR1-3 kinases in tumor progression and metastasis formation, as an inhibitor of both FGFR1/2 and VEGFR1-3, lucitanib has the potential benefit of targeting two relevant pro-angiogenic growth factors in targeted patient populations identified by molecular markers.

*Opportunity for Clovis*

Within the universe of FGFR-inhibitors, we were particularly attracted to the profile of lucitanib from a variety of perspectives:

- lucitanib is a very potent and selective inhibitor of FGFR1/2 and VEGFR1-3;
- patients whose tumors display suitable target pathway activation can be identified and may derive significant benefit from treatment;
- clinical data generated to date for lucitanib demonstrate proof of concept with objective responses commonly seen in FGFR1-amplified breast cancer patients, a target population where we believe pure FGFR inhibitors and pure VEGFR inhibitors have limited activity and utility;
- lucitanib has potential for use in combination with estrogen antagonists or as monotherapy in advanced breast cancer patients; and
- in squamous lung cancer where FGFR1 gene amplification is common, VEGFR has been validated clinically as a relevant therapeutic target, but FGFR inhibitors have shown only sporadic responses, thus suggesting a development opportunity for lucitanib, which meaningfully attacks both targets.

*Clinical Development of lucitanib*

The first-in-man clinical trial of lucitanib was initiated in Europe in July 2010 and is currently ongoing. The initial trial is an open-label, dose-escalation, Phase I/IIa study to determine the maximum tolerated dose (MTD), recommended dose, efficacy, pharmacokinetics and pharmacodynamics of oral lucitanib in adult patients with advanced solid tumors. The dose escalation phase started at 5mg once per day and went to 30mg dosed once per day. 20mg was identified as the MTD using a standard dose limiting toxicity (DLT) window definition, but in the heavily pre-treated study population dose reductions because of toxicity were frequent and, therefore, 15mg once per day has been adopted as a starting dose in one Phase II study. Overall, the toxicity profile observed to date is consistent with what was expected from preclinical studies, with hypertension, proteinuria and subclinical hypothyroidism requiring supplementation being commonly observed. Other common treatment-related events include asthenia and gastrointestinal symptoms (diarrhea, abdominal pain, nausea and vomiting). Subsequent to MTD identification, a dose expansion phase was initiated in defined populations expected to derive benefit from lucitanib. These patients were either FGFR or 11q amplified or angiogenesis inhibitor-sensitive patients. Six of twelve FGF aberrant breast cancer patients achieved RECIST partial responses with additional responses seen across other tumor types. Median PFS for these heavily pre-treated breast cancer patients (median of 6 prior lines of therapy) was 9.4 months.

*Development Strategy*

Based on the initial signals of activity and safety described above, a Phase II program is being initiated to explore lucitanib in multiple indications including a U.S. study in treatment refractory FGF aberrant breast cancer and a global study in FGFR-1 amplified metastatic squamous NSCLC. In parallel with planned Clovis-sponsored studies, a Servier-sponsored Phase II study of lucitanib monotherapy in patients with advanced breast cancer is expected to open to enrollment in the fourth quarter of 2013 in collaboration with The Breast International Group. This ex-US study is expected to enroll approximately 120 patients into 3 cohorts of 40 patients each: (1) FGFR-1 amplified, (2) 11q amplified, and (3) neither FGFR1 nor 11q amplified. This study will seek to determine whether the activity of lucitanib is limited to a biomarker-defined population of breast cancer tumors with FGF-aberrations or if a more broadly defined population may benefit. A European Phase Ib study is being developed by Servier to evaluate safety of lucitanib combined with fulvestrant, an estrogen receptor antagonist, in advanced breast cancer patients.

If these Phase II and Phase Ib combination studies are successfully completed, and assuming confirmation of the activity observed to date, we intend to pursue future development of lucitanib as monotherapy and/or in combination with estrogen antagonists, most likely in FGF-aberrant treatment refractory breast cancer. Other potential indications we may consider include squamous NSCLC, bladder, head and neck cancer, and other solid tumors with FGF-aberrancies.

Clinical development of lucitanib in patients with FGF-aberrant tumors will be accompanied by development of a diagnostic test designed to identify a selected patient population we believe to be the most likely to benefit. In the current Phase Ib and Phase II trial of lucitanib, Servier is using a third

party central lab to test tumor samples from prospective subjects to identify those with FGFR1 gene-amplified tumors. Neither we nor Servier have yet engaged a third party to develop any companion diagnostic that would be used in any future clinical trials of lucitanib or required for the registration and approval of lucitanib.

***Lucitanib Competition***

There are currently no approved drugs that specifically target both FGFR1 and VEGF. However, there are a number of FGFR inhibitors in development including Novartis dovitinib, currently in Phase I/II studies, AstraZeneca s AZD4547, currently in Phase II trials, Novartis BGJ 398, currently in Phase I trials, Johnson and Johnson s JNJ-42756493, currently in Phase I trials, Eli Lilly s LY 2874455, currently in a Phase I trial, Debiopharm s Debio 1357, currently in a Phase I trial, and GlaxoSmithKline s GSK3052230, currently in a Phase I trial.

**Product License Agreements**

***Advenchen Laboratories LLC***

In October 2008, EOS entered into an exclusive license agreement with Advenchen Laboratories LLC (as amended through the date hereof, the Advenchen Agreement ) to develop and commercialize lucitanib on a global basis, excluding China. If and when commercial sales commence, EOS is obligated to pay Advenchen tiered royalties at percentage rates in the mid-single digits on net sales of lucitanib, based on the volume of annual net sales achieved. In addition, after giving effect to the first and second amendments to the Advenchen Agreement, EOS is required to pay to Advenchen a percent in the mid-twenties of any consideration, excluding royalties, received by EOS from sublicensees, in lieu of the milestone obligations set forth in the agreement. EOS is obligated under the Advenchen Agreement to use commercially reasonable efforts to develop and commercialize at least one product containing lucitanib, and EOS is responsible for all remaining development and commercialization costs for lucitanib.

The Advenchen Agreement will remain in effect until the expiration of all of EOS royalty obligations to Advenchen, determined on a product-by-product and country-by-country basis, unless EOS elects to terminate the Advenchen Agreement earlier. If EOS fails to meet its obligations under the Advenchen Agreement and is unable to cure such failure within specified time periods, Advenchen can terminate the Advenchen Agreement, resulting in a loss of our rights to lucitanib.

The foregoing description of the Advenchen Agreement does not purport to be complete and is qualified in its entirety by reference to the Advenchen Agreement, which is filed as Exhibit 10.1 hereto and is incorporated herein by reference.

***Les Laboratoires Servier***

In September 2012, EOS entered into a collaboration and license agreement with Les Laboratoires Servier and Institut de Recherches Internationales Servier (the Servier Agreement ) whereby EOS sublicensed to Servier exclusive rights to develop and commercialize lucitanib in all countries outside of the U.S., Japan, and China. In exchange for these rights, EOS received an upfront payment of 45 million. Further, EOS is entitled to receive additional payments on the achievement of specified development, regulatory and commercial milestones up to 100 million in the aggregate. In addition, EOS is entitled to receive sales milestone payments if specified annual sales targets for lucitanib are met, each of which relates to annual sales targets of 250 million and above, which, in the aggregate, could amount to total milestone payments of 250 million. EOS is also entitled to receive royalties at percentage rates ranging from low double digits to mid-teens on sales of lucitanib by Servier.

Each of EOS and Servier are obligated to use diligent efforts to develop a product containing lucitanib and to carry out the activities assigned to it under a global development plan agreed to between the parties. Servier is responsible for

all of the global development costs for lucitanib up to 80 million, pursuant to a mutually-agreed upon development plan. Cumulative global development costs, if any, in excess of 80 million will be shared between EOS and Servier.

The Servier Agreement will remain in effect until the expiration of all of Servier s royalty obligations to us, determined on a product-by-product and country-by-country basis, unless Servier elects to terminate the Servier Agreement earlier. If we fail to meet our obligations under the Servier Agreement and are unable to cure such failure within specified time periods, Servier can terminate the Servier Agreement, resulting in the granting of a perpetual license to Servier of rights to lucitanib.

The foregoing description of the Servier Agreement does not purport to be complete and is qualified in its entirety by reference to the Servier Agreement, which is filed as Exhibit 10.2 hereto and is incorporated herein by reference.

**Patents and Proprietary Rights**

Composition of matter patent protection for lucitanib and a group of structurally related compounds is issued in the United States and is pending in Japan. In the United States, the composition of matter patent will expire in 2030. We believe that patent term extension could be available to extend our composition of matter patent up to five years beyond the scheduled expiration pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act. There is also a method of use patent for lucitanib and a group of structurally related compounds issued in the United States. Additionally, patent applications directed to methods of manufacturing lucitanib are pending in the United States and Japan.

**Manufacturing**

The active pharmaceutical ingredient for lucitanib is currently being manufactured at a third party contract manufacturer. To date, the current production process has been sufficient to satisfy immediate clinical demands. Additional development work may be performed to further optimize the active pharmaceutical ingredient manufacturing process.

The finished drug product for lucitanib is currently being manufactured at a third party contract manufacturer. The current product and process are sufficiently developed to meet immediate clinical demands. Additional development work is being performed to optimize the drug product formulation and manufacturing process to meet projected clinical and commercial requirements. Identification of an acceptable commercial formulation, suitable manufacturing process, and manufacturing site to prepare that formulation are critical to the successful development of lucitanib. Additional scale-up work and/or additional production capacity will be necessary to support larger clinical development or commercialization requirements.

**Facilities**

EOS is party to a lease for its headquarters in Milan, Italy, used primarily for corporate functions, with a six-month term expiring on March 31, 2014.

**Employees**

EOS and its subsidiary, together, have two full time employees, neither of whom is represented by labor unions or covered by collective bargaining agreements (other than the national collective agreement for the chemical and pharmaceutical sector in Italy).

**Legal Proceedings**

EOS is not currently engaged in any material legal proceedings.

**Item 3.02 Unregistered Sales of Equity Securities**

The description of the Stock Purchase Agreement set forth in Item 1.01 and Item 2.01 above is incorporated by reference into this Item 3.02. Pursuant to the terms and conditions of the Stock Purchase Agreement, on November 19, 2013, the Company issued to the Sellers an aggregate of 3,713,731 shares of Company Common Stock as part of the consideration for the purchase of EOS. The Company offered and sold the Company Common Stock in reliance on the

exemption from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the Securities Act ) and/or Rule 506 of Regulation D promulgated under the Securities Act, based on the nature of the investors and certain representations made to the Company.

**Item 9.01 Financial Statements and Exhibits.**

(a) Financial Statements of Business Acquired

The audited balance sheets of EOS S.p.A. as of December 31, 2012 and 2011, the related statements of operations, stockholders equity and cash flows for the years in the three year period ended December 31, 2012, and the notes related thereto, and the related independent auditors report of KPMG S.p.A. and the unaudited balance sheet of EOS S.p.A. and subsidiary as of September 30, 2013, the related unaudited statements of operations and cash flows of EOS S.p.A. for the nine months ended September 30, 2013 and 2012, and the related unaudited statement of stockholders equity for the nine months ended September 30, 2013 and the notes related thereto are attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. Such financial statements of EOS S.p.A. were prepared in conformity with generally accepted accounting principles in Italy. Accounting principles generally accepted in Italy vary in certain significant respects from U.S. generally accepted accounting principles. Information relating to the nature and effect of such differences is presented in note 14 to the financial statements.

(b) Pro Forma Financial Information

The unaudited pro forma condensed combined financial information for the nine months ended September 30, 2013 and the year ended December 31, 2012, and the notes thereto, is attached as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference. The unaudited pro forma condensed combined financial information includes adjustments to convert the basis of the historical financial statements of EOS S.p.A. from accounting principles generally accepted in Italy to U.S. GAAP and to translate Euro amounts into U.S. dollars.

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 2.1 | Stock Purchase Agreement, dated as of November 19, 2013, by and among the Company, EOS, the Sellers listed on Exhibit A thereto and Sofinnova Capital V FCPR, acting in its capacity as the Sellers Representative.* |
| 4.1 | Registration Rights Agreement, dated as of November 19, 2013, by and between the Company and the Sellers signatory thereto. |
| 10.1 | Development and Commercialization Agreement, dated as of October 24, 2008, by and between Advenchen Laboratories LLC and Ethical Oncology Science S.p.A., as amended by the First Amendment, dated as of April 13, 2010 and the Second Amendment, dated as of July 30, 2012.** |
| 10.2 | Collaboration and License Agreement, dated as of September 28, 2012, by and between Ethical Oncology Science S.p.A. and Les Laboratoires Servier and Institut de Recherches Internationales Servier.** |
| 23.1 | Consent of KPMG S.p.A., Independent Registered Public Accounting Firm. |
| 99.1 | The audited balance sheets of EOS S.p.A. as of December 31, 2012 and 2011, the related statements of operations, stockholders equity and cash flows for each of the years in the three year period ended December 31 2012, and the notes related thereto, and the unaudited balance sheet of EOS S.p.A. and subsidiary as of September 30, 2013, the related unaudited statements of operations and cash flows of EOS S.p.A. for the nine months ended September 30, 2013 and 2012, and the related unaudited statement of stockholders equity for the nine months ended September 30, 2013 and the notes related thereto. |

99.2 The unaudited pro forma combined financial information for the nine months ended September 30, 2013 and the year ended December 31, 2012, and the notes thereto.

* The schedules referenced in the Stock Purchase Agreement have been omitted in accordance with Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule will be furnished supplementally to the Securities and Exchange Commission upon request.

** Pursuant to a request for confidential treatment, portions of these Exhibits have been redacted from the publicly filed documents and have been furnished separately to the Securities and Exchange Commission as required by Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms believes, estimates, anticipates, expects, plans, intends, m might, will, should, approximately or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this Current Report on Form 8-K and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us. By their nature, forward-looking statements involve risks and uncertainties, including, among others, the uncertainties inherent in the initiation of future clinical trials, availability of data from ongoing clinical trials, expectations for regulatory approvals, and other matters that could affect the availability or commercial potential of our drug candidates because they relate to events, competitive dynamics, and industry change and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained herein. Factors that could cause or contribute to such differences include, but are not limited to, those factors set forth under Risk Factors in our most recent Annual Report on Form 10-K, as revised or supplemented by our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. As a result, you should not place undue reliance on these forward-looking statements. We undertake no obligation to revise these forward-looking statements to reflect future events or developments.

**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.

**CLOVIS ONCOLOGY, INC.**

November 19, 2013

By: /s/ Erle T. Mast
Name: Erle T. Mast
Title: Executive Vice President and Chief Financial Officer

**EXHIBIT INDEX**

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