CERUS CORP
Form 8-K
October 02, 2015

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 29, 2015

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**0-21937**	**68-0262011**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**

2550 Stanwell Drive

Concord, California 94520

(Address of principal executive offices) (Zip Code)

Registrant s telephone number, including area code: (925) 288-6000

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))

Item 1.01. Entry into a Material Definitive Agreement.

On September 29, 2015, Cerus Corporation (the Company) entered into an amendment (the Amendment) to that certain Loan and Security Agreement dated as of June 30, 2014 with Oxford Finance LLC (Oxford), as collateral agent, and the lenders party thereto (the Credit Agreement).

The Amendment extends the period during which the Company can draw down an additional advance of up to $10,000,000 (Term Loan C), if available, from December 31, 2015 to the earlier of (i) June 30, 2016 and (ii) 60 days after date on which the Company achieves consolidated trailing six months revenue at a specified threshold (the Revenue Event). Term Loan C would be available to the Company subject to the achievement of the Revenue Event. The Amendment also extends the interest-only period on all advances under the Credit Agreement through June 1, 2016, with an additional interest-only extension to December 1, 2016 if the Company achieves the Revenue Event for the period ending May 31, 2016.

The foregoing is only a brief description of the material terms of the Amendment, does not purport to be complete and is qualified in its entirety by reference to the full text of the Amendment, which will be filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2015.

Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information set forth under Item 1.01 above is hereby incorporated by reference into Item 2.03.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements related to the availability and funding under the Credit Agreement, the timing thereof and the satisfactions of the conditions thereto, including the Company s achievement of the Revenue Event. Actual results could differ materially from these forward-looking statements as a result of certain factors, including, without limitation: risks associated with the satisfaction of the conditions to the funding and the Company s ability to maintain (and otherwise comply with the covenants in) the Credit Agreement; risks associated with the commercialization and market acceptance of, and customer demand for, the INTERCEPT Blood System, including the risk that the negative sales impact from the strategic changes to the Company s distributor relationships could last longer or be more severe than anticipated and that the Company may otherwise not resume revenue growth in future periods; risks associated with the Company s lack of commercialization experience in the United States and its ability to develop and maintain an effective and qualified U.S.-based commercial organization, as well as the resulting uncertainty of its ability to achieve market acceptance of and otherwise successfully commercialize the INTERCEPT Blood System for platelets and plasma in the United States; risks related to the Company s ability to commercialize the Intercept Blood System in the United States without infringing on the intellectual property rights of others; risks related to the Company s ability to demonstrate to the transfusion medicine community and other health care constituencies that pathogen reduction and the INTERCEPT Blood System are safe, effective and economical; the uncertain and time-consuming development and regulatory process, including the risks (a) that the Company may be unable to complete the additional development and other activities necessary to support the potential CE Mark submission for the INTERCEPT Red Blood Cell system in a timely manner or at all, and may otherwise be unable to obtain any regulatory approvals for the INTERCEPT Red Blood Cell system, (b) that the Company may be unable to comply with the FDA s post-approval requirements for the INTERCEPT platelet and plasma systems, which could result in a loss of U.S. marketing approval for the INTERCEPT platelet and plasma

systems and (c) related to the Company s ability to expand the label claims and product configurations for the INTERCEPT platelet and plasma systems in the U.S. and elsewhere, which will require additional regulatory approvals; adverse market and economic conditions, including continued or more severe adverse fluctuations in foreign exchange rates and/or weakening economic conditions in the markets where the Company sell its products; the Company s reliance on third parties to market, sell, distribute and maintain its products; the Company s ability to maintain an effective manufacturing supply chain, including the ability of its manufacturers to comply with extensive FDA and foreign regulatory agency requirements; the impact of legislative or regulatory healthcare reforms that may make it more difficult and costly for the Company to obtain regulatory approval of its products and to produce, market and distribute its products after approval is obtained; as well as other risks detailed in the Company s filings with the Securities and Exchange Commission, including the Company s Quarterly Report on Form 10-Q for the three months ended June 30, 2015, filed with the SEC on August 7, 2015. The Company disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this Current Report on Form 8-K.

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.

CERUS CORPORATION

Dated: October 2, 2015

By: /s/ Chrystal Menard
Chrystal Menard
Chief Legal Officer and General Counsel