CURIS INC
Form 8-K
January 21, 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): January 18, 2015

Curis, Inc.

(Exact name of registrant as specified in charter)

Delaware	**000-30347**	**04-3505116**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4 Maguire Road

Lexington, MA **02421**
(Address of principal executive offices) **(Zip Code)**
Registrant s telephone number, including area code: (617) 503-6500

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 (*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))

Cautionary Note Regarding Forward Looking Statements

This Current Report on Form 8-K and the exhibit attached hereto contain forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may contain the words believes, expects, anticipates, plans, seeks, estimates, assumes, will, may, could, target, or the negative of these terms or other similar expressions. These forward-looking statements include, among others, statements about our business, plans, prospects and strategies and our expectations regarding our Collaboration Agreement (as defined below) with Aurigene (as defined below), including our goals with respect to programs (as defined below). These forward-looking statements are not guarantees of future performance and involve risks, uncertainties, assumptions and other important factors that may cause actual results to be materially different from those indicated by such forward-looking statements. For example, we face a number of risks inherent in the research, development or commercialization of novel drugs to treat cancer and may not be able to successfully advance the development of our drug candidates in the time frames we project, if at all. There can be no guarantee that the Collaboration Agreement will continue for its full term, that we or Aurigene will maintain the financial resources necessary to continue financing our respective portion of research, development and commercialization costs or that we or Aurigene will successfully discover, develop or commercialize drug candidates under the collaboration. Our expectations could also be affected by risks and uncertainties relating to a failure of Curis or Aurigene to fully perform under the Collaboration Agreement and/or any early termination of the Collaboration Agreement, adverse results of clinical trials and preclinical studies that are the subject of the collaboration, including subsequent analysis of existing data and new data received from ongoing and future studies, the content and timing of decisions made by the U.S. Food & Drug Administration and other regulatory authorities, investigational review boards at clinical trial sites, and publication review bodies, and our inability to enroll patients in clinical trials that may be initiated under the collaboration. We may also experience adverse results, delays and/or failures in our other drug development programs. We face risks and uncertainties relating to the successful commercialization of Erivedge® (vismodegib), which is currently being commercialized and sold by Genentech Inc. and F. Hoffmann-La Roche Ltd under our collaboration with Genentech. We also face risks relating to our wholly-owned subsidiary s Erivedge royalty-collateralized loan transaction, including the risk that it may not receive sufficient levels of royalty revenue from sales of Erivedge to satisfy the debt obligation or may otherwise lose its rights to royalties and royalty-related payments as a result of a foreclosure of the loan. We will require substantial additional capital to fund our business, including additional clinical trials of CUDC-907 and such capital may not be available on reasonable terms, or at all. We may not obtain or maintain necessary patent protection and could become involved in expensive and time consuming patent litigation and interference proceedings. We face substantial competition. Unstable market and economic conditions may adversely affect our financial condition and our ability to access capital to fund the growth of our business. We also face other important risks relating to our business, operations, financial condition and future prospects that are discussed in our Quarterly Report on Form 10-Q for the period ended September 30, 2014 and other filings that we periodically make with the Securities and Exchange Commission.

The forward-looking statements included in this Current Report on Form 8-K and the exhibit attached hereto represent our views as of the date of this Form 8-K. We anticipate that subsequent events and developments will cause our views to change. While we may elect to update these forward-looking statements in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this Form 8-K.

Item 1.01. Entry into a Material Definitive Agreement
Transaction with Aurigene Discovery Technologies Limited

Collaboration, License and Option Agreement

Transaction Overview. On January 18, 2015, we entered into a Collaboration, License and Option Agreement (the Collaboration Agreement) with Aurigene Discovery Technologies Limited (Aurigene) for the discovery, development and commercialization of compounds either (i) by specifically modulating immuno-modulating molecular targets (Immuno-oncology), or (ii) by specifically modulating the activity of a cellular protein whose encoding gene is altered in a population of human cancers (Precision Oncology). Under the Collaboration Agreement, Aurigene also grants us options to obtain exclusive, royalty-bearing licenses under relevant Aurigene technology to develop, manufacture and commercialize products containing certain of such compounds.

Under the Collaboration Agreement, a steering committee composed of representatives of both parties will recommend target(s) in Immuno-oncology or Precision Oncology for the conduct of discovery, research and preclinical development programs with respect to compounds active against such selected target(s). Aurigene will be responsible for performing all preclinical activities for each program in accordance with a written plan, and has agreed to use commercially reasonable efforts to generate at least one development candidate that meets the criteriafor advancement into preclinical studies necessary for the filing of an investigational new drug application, or IND, including conducting IND-enabling toxicology studies and providing supply of such compound suitable for Phase 1 clinical trials.

The Collaboration Agreement specifies that the first two programs will target the modulation of Interleukin-1 receptor-associated kinase 4, or IRAK4, and programmed death ligand 1, or PD-L1 pathway, respectively. We anticipate that at least two additional programs will be recommended by the steering committee no later than two years after the effective date of the Collaboration Agreement, and our goal is to have the steering committee recommend as many additional programs as feasible, in order for Aurigene to initiate or continue the relevant preclinical activities to be described in each written plan.

For each program, Aurigene has granted us an exclusive option, exercisable within 90 days after Aurigene delivers the relevant data regarding a development candidate to us, to obtain an exclusive, royalty-bearing license to develop, manufacture and commercialize compounds from such program, including the development candidate, and products containing such compounds, anywhere in the world with the exception of India and Russia (the Curis Territory). Upon exercise of the option for a particular program, Aurigene will grant us the license described above for such program, and we will grant Aurigene an exclusive, royalty-free, fully paid license under our relevant technology to develop, manufacture and commercialize compounds from such program and products containing such compounds in India and Russia (the Aurigene Territory).

For each program with respect to which we exercise the option to license (as described above), we are obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize at least one product in each of the U.S., specified countries in the European Union, and Japan (the Major Markets), and Aurigene is obligated to use commercially reasonable efforts to perform its obligations under the development plan for such licensed program in an expeditious manner.

Subject to specified exceptions, Aurigene and we have agreed to work exclusively with each other on the discovery, research, development and commercialization of programs and compounds within Immuno-oncology for approximately two years from the effective date of the Collaboration Agreement. At our option, and subject to specified conditions, we may extend such exclusivity for up to three additional one year periods by paying to Aurigene exclusivity option fees on an annual basis.

In addition, beyond the up-to five years of exclusivity described above, and subject to specified exceptions, Aurigene and we have agreed to work exclusively with each other on each program for which there are ongoing activities in research or development, or for which we have exercised our option to exclusively license (as described above) and we or our affiliates or sublicensees are actively developing or commercializing a compound or product from such program in a Major Market, subject to our payment of an annual exclusivity fee on a program-by-program basis.

For each product that may be commercialized, we have granted Aurigene the right, subject to certain conditions, to nominate one global supplier of drug substance or drug product, to provide up to 50% of the total requirements in the Curis Territory.

Research, Option Exercise Fees and Milestone Payments. In addition to issuing shares of our common stock to Aurigene in partial consideration for the rights granted under the Collaboration Agreement, as further described below in this Item 1.01 under the heading Stock Purchase Agreement, we have agreed to make the following payments to

Aurigene:

(i) for the first two programs: up to $52.5 million per program, including up to $10 million for an option exercise fee, a preclinical milestone and development milestones, as well as specified approval and commercial milestones, plus specified additional payments for approvals for additional indications, if any;

(ii) for the third and fourth programs: up to $50 million per program, including up to $7.5 million for research fees, an option exercise fee, a preclinical milestone and development milestones, as well as specified approval and commercial milestones, plus specified additional payments for approvals for additional indications, if any; and

(iii) for any program thereafter: up to $140.5 million per program, including up to a total of $53 million for research fees, an option exercise fee, , a preclinical milestone and development milestones, as well as specified filing, approval and commercial milestones, plus specified additional payments for approvals for additional indications, if any.

Royalties on Net Sales by Curis. We have agreed to pay Aurigene tiered royalties on our and our affiliates annual net sales of products at percentage rates ranging from the high single digits up to 10%, subject to specified reductions.

Amounts that we Receive from Sublicensees. We have agreed to make the following payments to Aurigene upon our entry into sublicense agreements on any program(s):

(i) with respect to amounts that we and our affiliates receive from sublicensees with respect to the grant of a sublicense of a licensed program in the U.S. or the European Union, a declining percentage of non-royalty sublicense revenues that is dependent on the stage of the most advanced product for such licensed program at the time the sublicense is granted, including for example 25% of such amounts following our initiation of Phase 2 clinical study and 15% of such amounts after initiation of the first pivotal study. This sharing will also extend to royalties that we receive from sublicensees, subject to minimum royalty percentage rates that we are obligated to pay to Aurigene, which generally range from mid-to-high single-digit royalty percentage rates up to 10%;

(ii) with respect to sublicensing revenues we and our affiliates receive from sublicensees with respect to the grant of a sublicense of a licensed program in Asia, 50% of such sublicensing revenues, including both non-royalty sublicensee revenues and royalties that we receive from sublicensees; and

(iii) with respect to non-royalty sublicensing revenues we and our affiliates receive from sublicensees with respect to the grant of a sublicense of a licensed program outside of the U.S., the European Union and Asia, a percentage of such non-royalty sublicense revenues ranging from 30% to 50%. We are also obligated to share 50% of royalties that we receive from sublicensees that we receive in these territories.

Our royalty payment obligations (including with respect to royalties on sales by sublicensees) under the Collaboration Agreement with respect to a product in a country will expire on a product-by-product and country-by-country basis on the later of (i) expiration of the last-to-expire valid claim of the Aurigene patents covering the manufacture, use or sale of such product in such country and (ii) 10 years from the first commercial sale of such product in such country (the Royalty Term).

Term and Termination. The term of the Collaboration Agreement begins upon signing and, unless earlier terminated, will expire upon either: (i) 90 days after the completion by Aurigene of its obligations under all research plans if we have not exercised the option with respect to at least one program by such time; or (ii) expiration of the last-to-expire Royalty Term for any and all products. Upon expiration (but not on earlier termination) of the Collaboration Agreement, all licenses granted by Aurigene to us that were in effect immediately prior to such expiration shall survive on a non-exclusive, royalty-free, fully paid, irrevocable, perpetual basis.

The Collaboration Agreement may be terminated, either in its entirety or with respect to a particular program, by either Aurigene or us for uncured material breach by the other party, other than an uncured material breach by the other party of its diligence obligations with respect to a program or licensed program (a Diligence Breach). If an

uncured material breach other than a Diligence Breach (a Non Diligence Breach) relates to a particular program or licensed program, the non breaching party may terminate the Collaboration Agreement only with respect to that program or licensed program. However, after initiation of the first pivotal clinical trial of a product for a licensed program, Aurigene may not terminate the Collaboration Agreement with respect to such licensed program for an uncured Non Diligence Breach by us, except in the case of our uncured material breach of our payment obligations with respect to such licensed program, but Aurigene may pursue any and all remedies that may be available to it at law or in equity as a result of such breach. Similarly, after initiation of the first pivotal clinical trial of a product for a licensed program, we may not terminate the Collaboration Agreement with respect to the license we have granted Aurigene for the Aurigene Territory for such licensed program for an uncured Non Diligence Breach by Aurigene, but we may pursue any and all remedies that may be available to us at law or in equity as a result of such breach.

On a program-by-program basis, we may terminate the Collaboration Agreement as it relates to a program or licensed program for an uncured Diligence Breach by Aurigene with respect to such program or licensed program, and Aurigene may terminate the Collaboration Agreement as it relates to a licensed program for an uncured Diligence Breach by us with respect to such licensed program.

In addition, we may terminate the Collaboration Agreement in its entirety or as it relates to a particular program or licensed program or on a country-by-country basis, for any reason or for no reason at any time upon 60 days prior written notice to Aurigene.

In the event of termination of the Collaboration Agreement in its entirety before we have exercised the option for any program, or termination of the Collaboration Agreement as it relates to any program prior to exercise of the option for such program, all rights and licenses granted by either Aurigene or us to the other party with respect to such program under the Collaboration Agreement (including the option for such program) will automatically terminate.

If the Royalty Term with respect to a product for any licensed program in any country has expired on or before any termination of the Collaboration Agreement in its entirety or as to such licensed program, the license granted by Aurigene to us with respect to such product in such country, as well as the corresponding license granted to Aurigene in the Aurigene Territory (an Aurigene Territory License), shall survive such termination of the Collaboration Agreement.

Solely in the event of termination of the Collaboration Agreement by Aurigene for our uncured Non Diligence Breach or our uncured Diligence Breach, or our termination of the Collaboration Agreement for convenience, the following will apply to any program that was a licensed program immediately prior to such termination:

(i) our license with respect to any licensed program that is not a Terminated Program (defined below), either in the entire Curis Territory or in countries of the Curis Territory outside of the Terminated Region (defined below), as applicable, shall continue in full force and effect, subject to all terms and conditions of the Collaboration Agreement, including our payment obligations;

(ii) our license with respect to any Terminated Program, either in the entire Curis Territory or in the Terminated Region, as applicable, shall terminate and revert to Aurigene;

(iii) we will grant Aurigene a perpetual, royalty-free (except for pass-through royalties and milestone payments payable by us under licenses to third party patent rights with respect to products developed or commercialized by or on behalf of Aurigene) license, with the right to sublicense, under our relevant patent rights and other technology solely to develop, manufacture and commercialize compounds and products for any Terminated Program, either in the Curis Territory or in the Terminated Region, as applicable. The foregoing license will be non-exclusive with respect to our patent rights and exclusive with respect to our other technology;

(iv) we will grant to Aurigene a right of first negotiation, exercisable within 90 days after termination, to obtain an exclusive, royalty-bearing license, with the right to sublicense, under our relevant patent rights solely to develop, manufacture and commercialize compounds and products for any Terminated Program, either in the Curis Territory or in the Terminated Region, as applicable, upon commercially reasonable terms and conditions to be negotiated in good faith by the parties;

(v) we will perform other specified activities and actions reasonably necessary for Aurigene to develop, manufacture and commercialize compounds and Products for any Terminated Program, either in the Curis Territory or in the Terminated Region, as applicable; and

(vi) the applicable license to Aurigene will survive termination.

For purposes of the foregoing, Terminated Program means: (i) in the case of termination of the Collaboration Agreement in its entirety by Aurigene for our uncured Non Diligence Breach, any program that was a licensed program immediately prior to such termination, but excluding, except in the case of our uncured material breach of our payment obligations with respect to such licensed program, any such licensed program for which initiation of the first pivotal clinical trial of a product has occurred prior to such termination; (ii) in the case of any termination of the Collaboration Agreement as to a particular licensed program by Aurigene either for our uncured Non Diligence Breach (to the extent termination as to such licensed program is permitted) or our uncured Diligence Breach, such licensed program; (iii) in the case of our termination of the Collaboration Agreement in its entirety for convenience, any program that was a licensed program immediately prior to such termination; or (iv) in the case of our termination of the Collaboration Agreement as to a particular licensed program for convenience, such licensed program; provided, however, that, in the case of the preceding clauses (iii) and (iv), if our termination of the Collaboration Agreement in its entirety or as to a particular licensed program for convenience was with respect only to a particular country or subset of countries within the Curis Territory (as applicable, a Terminated Region), the applicable licensed program(s) shall be considered Terminated Program(s) only in the Terminated Region but shall remain licensed program(s) in the rest of the Curis Territory.

Stock Purchase Agreement

In connection with the Collaboration Agreement, we issued to Aurigene 17,120,131 shares of our common stock (the Shares) in partial consideration for the rights granted to us under the Collaboration Agreement. The Shares were issued pursuant to a Stock Purchase Agreement with Aurigene dated January 18, 2015 (the Purchase Agreement). After giving effect to the sale of the Shares, Aurigene will beneficially own approximately 16.6% of our outstanding common stock.

Pursuant to the Purchase Agreement, Aurigene has agreed that the shares shall be subject to a lock-up restriction such that Aurigene will not, during the period ending on January 18, 2017, without our prior written consent, (a) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, contract to dispose of, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Securities Exchange Act of 1934 and the rules and regulations of the SEC promulgated thereunder, with respect to any of the Shares, (b) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such Shares, in cash or otherwise, or (c) publicly announce an intention to effect any transaction specified in clause (a) or (b). Notwithstanding the foregoing, Aurigene is permitted to take any of the actions described under clauses (a)-(c) with respect to:

(i) up to an aggregate of

(A) 25% of the Shares from and after July 18, 2015,

(B) 50% of the Shares from and after January 18, 2016, and

(C) 75% of the Shares from and after July 18, 2016, and

(ii) any or all of the Shares after any public announcement with respect to an acquisition of Curis by a third party or any change of control of Curis.

Registration Rights Agreement

In connection with the issuance of the Shares, we entered into a Registration Rights Agreement with Aurigene dated January 18, 2015 (the Registration Rights Agreement). Pursuant to the terms of the Registration Rights Agreement, we have agreed to file a resale registration statement on Form S-3 (or such other form as is then available to effect a resale registration of the Shares) with the SEC on or prior to April 20, 2015, to register for resale the Shares. Additionally, at any time after July 18, 2015, Aurigene may request registration of all or a portion of the Shares on Form S-3 (or such other form as is then available to effect a registration of the Shares for sale to the public), subject to specified conditions, including that no such registration will be effected for any Shares that are then subject to the lock-up agreement described above. Subject to specified conditions, we are not required to effect more than two such demand registrations for Aurigene. We have also given Aurigene piggyback registration rights such that whenever we propose to register shares of our common stock for our own account or the account of others, Aurigene will have the right to include some or all of its Shares in such registration, provided that no such registration will be effected for any Shares that are then subject to the lock-up agreement described above. The Registration Rights Agreement also contains other customary terms and conditions of the parties with respect to the registration of the Shares.

The foregoing summary descriptions of the Collaboration Agreement, Purchase Agreement and Registration Rights Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of such agreements, each of which will be filed as exhibits to our Annual Report on Form 10-K for the year ended December 31, 2014.

Item 3.02. Unregistered Sales of Equity Securities

The information set forth in Item 1.01 above under the caption Stock Purchase Agreement is incorporated herein by reference.

The Shares will be issued in reliance on the exemption from the registration under (a) Section 4(a)(2) of the Securities Act of 1933, as amended (the Securities Act), for a transaction by an issuer not involving any public offering within the meaning of Section 4(a)(2) and (b) under Regulation S promulgated under the Securities Act (Regulation S) in that the offer and sale of the Shares is being made to a person outside of the United States without registration, no directed selling efforts have been made in the United States, and the additional conditions of Regulation S have been satisfied.

Item 8.01. Other Events

On January 21, 2015, we issued a press release announcing our transaction with Aurigene, including our entry into the Collaboration Agreement, the Stock Purchase Agreement and the Registration Rights Agreement. The full text of the press release issued in connection with this announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d)

The exhibit to this Current Report on Form 8-K is listed in the Exhibit Index attached hereto.

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.

By: /s/ Michael P. Gray
Michael P. Gray

Chief Financial and Chief Business Officer

Date: January 21, 2015

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of Curis, Inc. dated January 21, 2015