CURIS INC
Form 10-Q
November 09, 2015
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark one)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2015

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number: 000-30347

CURIS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3505116**
(State or Other Jurisdiction of	**(I.R.S. Employer**
Incorporation or Organization)	**Identification No.)**
4 Maguire Road	
Lexington, Massachusetts	**02421**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant s Telephone Number, Including Area Code: (617) 503-6500

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x Yes ¨ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x Yes ¨ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ¨ Yes x No

As of November 5, 2015, there were 128,394,655 shares of the registrant s common stock outstanding.

Table of Contents

CURIS, INC. AND SUBSIDIARIES QUARTERLY REPORT ON FORM 10-Q

INDEX

Table of Contents

Item 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
CURIS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

	September 30, 2015	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 28,658,916	$ 7,747,411
Investments	64,811,477	42,002,782
Short-term investment restricted		13,877
Accounts receivable	2,318,202	1,960,995
Prepaid expenses and other current assets	818,176	489,844
Total current assets	96,606,771	52,214,909
Property and equipment, net	315,470	407,738
Long-term investments		788,768
Long-term investment restricted	152,610	152,610
Goodwill	8,982,000	8,982,000
Other assets	56,025	67,544
Total assets	$ 106,112,876	$ 62,613,569
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 2,568,945	$ 2,349,183
Accrued liabilities	1,873,842	2,007,699
Current portion of long-term debt, net	4,860,418	5,709,985
Total current liabilities	9,303,205	10,066,867
Long-term debt, net	20,668,112	22,589,058
Other long-term liabilities	148,745	174,018
Total liabilities	30,120,062	32,829,943
Commitments		
Stockholders Equity:		
Common stock, $0.01 par value 225,000,000 shares authorized; 129,617,501 shares issued and 128,394,655 shares outstanding at September 30, 2015; 87,253,657 shares issued and 86,030,811 shares outstanding at December 31, 2014	1,296,175	872,537
Additional paid-in capital	901,242,489	810,001,410

Treasury stock (at cost, 1,222,846 shares)	(1,524,029)	(1,524,029)
Accumulated deficit	(825,075,335)	(779,555,295)
Accumulated other comprehensive loss	53,514	(10,997)
Total stockholders equity	75,992,814	29,783,626
Total liabilities and stockholders equity	$ 106,112,876	$ 62,613,569

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents

CURIS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
Royalties	$ 2,292,608	$ 1,783,271	$ 5,997,514	$ 4,895,454
Research and development, net	(247,641)	(18,407)	(211,711)	(44,672)
License fees				3,000,000
Total revenues	2,044,967	1,764,864	5,785,803	7,850,782
Costs and Expenses:				
Cost of royalty revenues	116,145	89,295	303,209	246,280
Research and development	4,001,069	3,705,365	14,658,017	10,180,271
In-process research and development			24,347,815	
General and administrative	2,771,496	2,723,235	9,711,470	8,475,392
Total costs and expenses	6,888,710	6,517,895	49,020,511	18,901,943
Loss from operations	(4,843,743)	(4,753,031)	(43,234,708)	(11,051,161)
Other Income/(Expense):				
Interest income	127,329	38,881	251,692	129,120
Interest expense	(826,710)	(933,903)	(2,537,024)	(2,834,609)
Change in fair value of warrant liability		67,910		716,786
Total other expense	(699,381)	(827,112)	(2,285,332)	(1,988,703)
Net loss	$ (5,543,124)	$ (5,580,143)	$ (45,520,040)	$ (13,039,864)
Net loss per common share (basic and diluted)	$ (0.04)	$ (0.06)	$ (0.37)	$ (0.15)
Weighted average common shares (basic and diluted)	128,392,413	86,004,857	121,634,415	85,962,415

Total comprehensive loss	$ (5,488,033)	$ (5,584,080)	$ (45,455,529)	$ (13,029,416)

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

CURIS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine Months Ended September 30,	
	2015	**2014**
Cash Flows from Operating Activities:		
Net loss	$ (45,520,040)	$ (13,039,864)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	123,056	114,058
Stock-based compensation expense	2,874,585	2,245,565
Change in fair value of warrant liability		(716,786)
Non-cash interest expense on investments	118,674	108,511
Amortization of debt issuance costs	44,296	68,716
Issuance of common stock in consideration for rights granted under Aurigene collaboration agreement (see Note 4(b))	23,968,183	
Payment-in kind interest on Curis Royalty s debt		(713,968)
Net gain on sale of fixed assets and equipment	(16,545)	(1,750)
Changes in operating assets and liabilities:		
Accounts receivable	(357,207)	(362,131)
Prepaid expenses and other assets	(338,526)	(168,343)
Accounts payable and accrued liabilities	75,589	345,474
Total adjustments	26,492,105	919,346
Net cash used in operating activities	(19,027,935)	(12,120,518)
Cash Flows from Investing Activities:		
Purchase of investments	(95,595,171)	(38,284,246)
Sale of investments	73,521,081	49,353,851
Decrease in restricted cash	13,877	13,877
Purchases of property and equipment	(47,985)	(65,764)
Proceeds from sale of equipment	18,785	1,750
Net cash (used in)/provided by investing activities	(22,089,413)	11,019,468
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock associated with offerings, net of issuance costs (see Note 8(a))	64,619,407	
Proceeds from issuance of common stock under share-based compensation plans	202,542	256,843
Payment on Curis Royalty s principal obligations	(2,793,096)	(813,810)
Net cash provided by/(used in) financing activities	62,028,853	(556,967)

Net Increase/(Decrease) in Cash and Cash Equivalents		20,911,505		(1,658,017)
Cash and Cash Equivalents, Beginning of Period		7,747,411		9,591,487
Cash and Cash Equivalents, End of Period	$	28,658,916	$	7,933,470

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

CURIS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

1. Nature of Business

Curis, Inc. is a biotechnology company seeking to develop and commercialize innovative drug candidates for the treatment of human cancers. As used throughout these condensed consolidated financial statements, the term the Company refers to the business of Curis, Inc. and its wholly owned subsidiaries, except where the context otherwise requires, and the term Curis refers to Curis, Inc.

The Company conducts its research and development programs both internally and through strategic collaborations. The Company s most advanced drug candidate is CUDC-907, an orally-available, small molecule inhibitor of histone deacetylase, or HDAC, and phosphatidylinositol-3-kinase, or PI3K enzymes, that is being investigated in clinical studies in patients with lymphomas and solid tumors.

In January 2015, the Company entered into an exclusive collaboration agreement focused on immuno-oncology and selected precision oncology targets with Aurigene Discovery Technologies Limited, or Aurigene (see Note 4(b)). The collaboration is comprised of multiple programs, in which Curis has the option to exclusively license compounds once a development candidate is nominated within each respective program. In October 2015, the Company exercised options to license the first two programs under this collaboration. The first licensed program is focused on the development of orally-available small molecule antagonists of programmed death -1 (PD-1) and V-domain Ig suppressor of T cell activation (VISTA) in the immuno-oncology field. The Company has named CA-170, a PD-L1/VISTA antagonist, as the development candidate from this program. The second licensed program is focused on orally-available small molecule inhibitors of Interleukin-1 receptor-associated kinase 4 (IRAK4) in the precision oncology field. In addition, in October 2015 the Company selected a second preclinical program within the immuno-oncology part of the collaboration, the third overall collaboration program, that is focused on evaluating small molecule antagonists with dual PD-1 and T-cell immunoglobulin and mucin domain containing protein-3 (TIM-3) targeting properties.

The Company is also party to a collaboration with F. Hoffmann-La Roche Ltd, or Roche, and Genentech Inc., or Genentech, a member of the Roche Group, under which Roche and Genentech are commercializing Erivedge® (vismodegib), a first-in-class orally-administered small molecule Hedgehog signaling pathway inhibitor, in advanced basal cell carcinoma, or BCC. Roche and Genentech are continuing to develop Erivedge in less severe forms of BCC and have communicated plans to develop Erivedge in other non-oncology indications.

The Company s proprietary pipeline also includes CUDC-427, an orally-available, small molecule antagonist of inhibitor of apoptosis, or IAP proteins, and CUDC-305, a Heat Shock Protein 90, or HSP90, inhibitor. The Company currently intends to utilize its available resources for the continued development of CUDC-907 and drug candidates it licenses under the collaboration with Aurigene. As such, the Company is seeking to collaborate with third parties for the further development of CUDC-427 and CUDC-305.

The Company operates in a single reportable segment, which is the research and development of innovative cancer therapeutics. The Company expects that any products that are successfully developed and commercialized would be used in the health care industry and would be regulated in the United States by the Food and Drug Administration, or FDA, and in overseas markets by similar regulatory authorities.

The Company is subject to risks common to companies in the biotechnology industry as well as risk that are specific to the Company s business, including, but not limited to: the Company s ability to advance and expand its research and development programs; the Company s reliance on Genentech and Roche to successfully commercialize Erivedge in the approved indication of advanced BCC and to progress its clinical development in indications other than BCC; the Company s reliance on Aurigene to successfully discover and preclinically develop drug candidates under the parties collaboration agreement; the Company s ability to obtain adequate financing to fund its operations; the ability of the Company s wholly owned subsidiary, Curis Royalty, LLC, or Curis Royalty, to satisfy the terms of its loan agreement with BioPharma Secured Debt Fund II Sub, S.à.r.l., a Luxembourg limited liability company managed by Pharmakon Advisors, or BioPharma-II; the Company s ability to obtain and maintain necessary intellectual property protection; development by the Company s competitors of new or better technological innovations; dependence on key personnel; the Company s ability to comply with regulatory requirements; and the Company s ability to execute on its overall business strategies.

The Company s future operating results will largely depend on the progress of drug candidates currently in its development pipeline and the magnitude of payments that it receives and makes under its current and potential future corporate collaborations. The results of the Company s operations may vary significantly from year to year and quarter to quarter and depend on a number of factors, including, but not limited to: the timing, outcome and cost of the Company s preclinical studies and clinical trials for its drug candidates; Roche and Genentech s ability to successfully

Table of Contents

commercialize Erivedge; positive results in Roche and Genentech s ongoing clinical trials; Aurigene s ability to successfully discover and develop preclinical programs under the Company s collaboration with Aurigene, as well as the Company s decision to exclusively license and further develop programs under this collaboration; and the Company s ability to successfully enter into one or more material outlicensing or collaboration agreements for its proprietary drug candidates.

The Company anticipates that existing cash, cash equivalents and investments at September 30, 2015 should enable it to maintain current and planned operations into 2017. The Company s ability to continue funding its planned operations beyond this period is dependent upon, among other things, its ability to control expenses and its ability to raise additional funds through equity or debt financings, the success of its collaboration with Genentech, including its receipt of additional contingent cash payments under this collaboration, new collaborations or other sources of financing. The Company may not be able to successfully raise additional funds or enter into or continue any corporate collaborations and the timing, amount and likelihood of the Company receiving payments under such collaborations is highly uncertain. If the Company is unable to obtain adequate financing, the Company may be required to reduce or delay spending on its research and/or development programs.

2. Basis of Presentation

The accompanying condensed consolidated financial statements of the Company have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. These statements, however, are condensed, and do not include all disclosures required by accounting principles generally accepted in the United States, or GAAP. For complete financial statements, the condensed consolidated financial statements should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the Securities and Exchange Commission on February 24, 2015.

In the opinion of the Company, the unaudited financial statements contain all adjustments (all of which were considered normal and recurring) necessary for a fair statement of the Company s financial position at September 30, 2015, the results of operations for the three- and nine-month periods ended September 30, 2015 and 2014, and the cash flows for the nine-month periods ended September 30, 2015 and 2014.

The preparation of the Company s condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts and disclosure of certain assets and liabilities at the balance sheet date. Such estimates include: performance obligations under the Company s collaboration agreements; the estimated repayment term of the Company s debt and related short- and long-term classification; the fair value of the Company s debt; the collectability of receivables; the carrying value of property and equipment and intangible assets; assumptions used in the Company s valuation of stock-based compensation; and, the value of certain investments and liabilities, including the Company s long-term warrant liability. Actual results may differ from such estimates.

These interim results are not necessarily indicative of results to be expected for a full year or subsequent interim periods.

3. Revenue Recognition

The Company is currently a party to a collaboration agreement with Genentech under which the Company records revenues. The terms of the Company s agreement with Genentech provide for Genentech to make a non-refundable

license fee payment, research and development funding payments, contingent cash payments based upon achievement of clinical development and regulatory objectives, and royalties on product sales if any products are successfully commercialized. For a complete discussion of the Company s revenue recognition policy, see Note 2(c) included in its 2014 Annual Report on Form 10-K.

4. Collaboration Agreements

(a) Genentech

In June 2003, the Company licensed its proprietary Hedgehog signaling pathway technologies to Genentech for human therapeutic use. The primary focus of the collaborative research plan has been to develop molecules that inhibit the Hedgehog signaling pathway for the treatment of various cancers. The collaboration is currently focused on the development of Erivedge, which is being commercialized by Genentech in the United States and by Roche in several other countries for the treatment of advanced basal cell carcinoma. Genentech s parent company, Roche, is also conducting additional exploratory Phase 2 studies in patients with less severe forms of basal cell carcinoma.

Table of Contents

Pursuant to the agreement, the Company is eligible to receive up to an aggregate of $115,000,000 in contingent cash milestone payments, exclusive of royalty payments, in connection with the development of Erivedge or another small molecule Hedgehog signaling pathway inhibitor, assuming the successful achievement by Genentech and Roche of specified clinical development and regulatory objectives. Of this amount, the Company has received $59,000,000 as of September 30, 2015. In June 2014, Roche filed an investigational new drug application for the use of Erivedge in patients with idiopathic pulmonary fibrosis, a non-oncology indication, resulting in a milestone payment of $3,000,000 to the Company. As a result of this milestone payment, the Company recognized revenue of $3,000,000 during the nine months ended September 30, 2014. No such payments were received during the three and nine months ended September 30, 2015.

In addition to the contingent cash milestone payments, the Company s wholly-owned subsidiary, Curis Royalty, is entitled to a royalty on net sales of Erivedge that ranges from 5% to 7.5%. The royalty rate applicable to Erivedge may be decreased by 2% (such that the applicable royalty rate will range from 3% to 5.5%) in certain specified circumstances, including when a competing product that binds to the same molecular target as Erivedge is approved by the applicable regulatory authority and is being sold in such country by a third party for use in the same indication as Erivedge or when there is no issued intellectual property covering Erivedge in a territory in which sales are recorded. During the third quarter of 2015, the U.S. Food and Drug Administration, or FDA, and the European Medicine Agency s Committee for Medicinal Products for Human Use, or CHMP, approved another Hedgehog signaling pathway inhibitor, sonidegib, which is marketed by Novartis, for use in locally advanced BCC. The Company and Genentech are currently evaluating the impact that these recent approvals will have on the royalty rate that Curis Royalty receives from Genentech.

Future royalty payments related to Erivedge will service the outstanding debt and accrued interest owed by Curis Royalty to BioPharma-II, up to specified quarterly caps for 2015, and thereafter until the debt is fully repaid (see Note 7). The Company recognized royalty revenues from Genentech s net sales of Erivedge of $2,292,608 and $1,783,271 during the three months ended September 30, 2015 and 2014, respectively, and $5,997,514 and $4,895,454 during the nine months ended September 30, 2015 and 2014, respectively. The Company recorded cost of royalty revenues in the costs and expenses section of its Condensed Consolidated Statements of Operations and Comprehensive Loss of $116,145 and $89,295 during the three months ended September 30, 2015 and 2014, respectively, and $303,209 and $246,280 during the nine months ended September 30, 2015 and 2014, respectively. Each of these amounts are comprised of 5% of the Erivedge royalties earned by Curis Royalty, which the Company is obligated to pay to university licensors. As further discussed in Note 7, the Company expects that all royalty revenues received by Curis Royalty from Genentech on net sales of Erivedge will be used by Curis Royalty to pay principal and interest under the loan that Curis Royalty received from BioPharma II, subject to the specified quarterly cap, until such time as the loan is fully repaid.

The Company recorded research and development revenue of $47,240 and $72,817 during the three months ended September 30, 2015 and 2014, respectively, and research and development revenue of $183,965 and $144,054 during the nine months ended September 30, 2015 and 2014, respectively, related to expenses incurred and paid by the Company on behalf of Genentech, and for which Genentech is obligated to reimburse the Company. Genentech incurred expenses of $296,380 and $94,118 during the three months ended September 30, 2015 and 2014, respectively, and expenses of $410,785 and $233,701 during the nine months ended September 30, 2015 and 2014, respectively, under this collaboration, for which the Company is obligated to reimburse Genentech, and which the Company has recorded as contra-revenues in its Condensed Consolidated Statements of Operations and Comprehensive Loss.

(b) Aurigene

Collaboration Overview. In January 2015, the Company entered into an exclusive collaboration agreement with Aurigene for the discovery, development and commercialization of small molecule compounds in the areas of immuno-oncology and selected precision oncology targets. Under the collaboration agreement, Aurigene granted the Company an option to obtain exclusive, royalty-bearing licenses to relevant Aurigene technology to develop, manufacture and commercialize products containing certain of such compounds.

In October 2015, the Company exercised options to license the first two programs under this collaboration, resulting in an aggregate one-time payment of $6,000,000 by the Company to Aurigene. The first licensed program is focused on the development of orally-available small molecule antagonists of PD-1

Table of Contents

and VISTA in the immuno-oncology field. The Company has named CA-170, a PD-L1/VISTA antagonist, as the development candidate from this program. The second licensed program is focused on orally-available small molecule inhibitors of Interleukin-1 receptor-associated kinase 4 (IRAK4) in the precision oncology field. Effective October 2015, the Company agreed to make additional payments to Aurigene totaling up to $2,000,000 for supplemental research, development and/or manufacturing activities in support of these two programs.

Also in October 2015, the Company named another preclinical program within the immuno-oncology part of the collaboration which is focused on evaluating small molecule antagonists with dual PD-1 and T-cell immunoglobulin and mucin domain containing protein-3 (TIM-3) targeting properties. The Company made a $2,000,000 milestone payment to Aurigene during the second quarter of 2015 related to the selection of this program.

The Company anticipates that it will select additional programs under this collaboration in the future, and the Company intends to have the collaboration s steering committee recommend as many additional programs as feasible in order for Aurigene to initiate or continue the relevant preclinical activities described in each program s written plan. For each program, Aurigene has granted the Company an exclusive option, exercisable within 90 days after Aurigene delivers the relevant data regarding a development candidate, 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, except for India and Russia. For the development, manufacture, and commercialization of compounds from a particular program and products containing such compounds in India and Russia, Aurigene will grant the Company the royalty-bearing license described above for such program, and the Company will grant Aurigene an exclusive, royalty-free, fully paid license under the Company s relevant technology upon exercise of the relevant option.

For each option to license (as described above) exercised by the Company, the Company is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for. 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 the Company have agreed to collaborate exclusively with each other on the discovery, research, development and commercialization of programs and compounds within immuno-oncology for an initial period of approximately two years from the effective date of the collaboration agreement. At the Company s option, and subject to specified conditions, it 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 and payment by the Company of an annual exclusivity fee on a program-by-program basis, Aurigene and the Company have agreed to collaborate exclusively with each other on each program for which there are ongoing activities in research or development, or for which the Company has exercised its option to acquire an exclusive license (as described above) and the Company or its affiliates or sublicensees are actively developing or commercializing a compound or product from such program in a major market.

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

Up-front Equity Issuance. In connection with the collaboration agreement, the Company issued to Aurigene 17,120,131 shares of its common stock in partial consideration for the rights granted to the Company under the collaboration agreement. The shares were issued pursuant to a stock purchase agreement with Aurigene dated

January 18, 2015.

Research Payments, Option Exercise Fees and Milestone Payments. The Company has agreed to make the following research, option exercise fees and milestone payments to Aurigene:

for the PD-1/VISTA and IRAK4 programs: up to $52,500,000 per program, including $3,000,000 for each option exercise, $3,000,000 upon acceptance of each IND filing by the Company and $4,000,000 upon dosing of the fifth patient in the first Phase 1 clinical trial in each program. In addition, Curis is obligated to make specified approval and commercial milestones, plus specified additional payments for approvals for additional indications, if any;

Table of Contents

for the third and fourth programs: up to $50,000,000 per program, including $2,000,000 for a program selection fee that the Company paid in May 2015 for the third program, $3,000,000 for an option exercise fee if the program is licensed and $2,500,000 upon acceptance of an IND filing by the Company. In addition, Curis is obligated to make development milestones, as well as specified approval and commercial milestones, plus specified additional payments for app