

CAPRICOR THERAPEUTICS, INC.

Form 10-Q

November 14, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

☐ Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended September 30, 2014

or

☐ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from to

Commission File Number: 001-34058

CAPRICOR THERAPEUTICS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

Delaware

(State or other jurisdiction of incorporation or organization)

88-0363465

(I.R.S. Employer Identification No.)

8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California

(Address of principal executive offices)

90211

(Zip Code)

(310) 358-3200

(Registrant's telephone number, including area code)

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. 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). 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.

Large accelerated filer Accelerated filer
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 No

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

As of November 12, 2014, there were 11,705,440 shares of the registrant's common stock, par value \$0.001 per share, issued and outstanding.

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;

- expectation of or dates for commencement of clinical trials, IND filings, similar plans or projections;

- the regulatory approval of our drug candidates;

- our use of clinical research centers, third party manufacturers and other contractors;

- our ability to find collaborative partners for research, development and commercialization of potential products;

- our ability to manufacture products for clinical and commercial use;

- our ability to protect our patents and other intellectual property;

- our ability to market any of our products;

- our history of operating losses;

- our ability to secure adequate protection for our intellectual property;

- our ability to compete against other companies and research institutions;

the effect of potential strategic transactions on our business;

acceptance of our products by doctors, patients or payors and the availability of reimbursement for our product candidates;

our ability to attract and retain key personnel; and

the volatility of our stock price.

We caution you that the forward-looking statements highlighted above do not encompass all of the forward-looking statements made in this Quarterly Report on Form 10-Q.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report on Form 10-Q primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors. Moreover, we operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report on Form 10-Q. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements. Additionally, final data may differ significantly from preliminary data reported in this document.

The forward-looking statements made in this Quarterly Report on Form 10-Q relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Quarterly Report on Form 10-Q to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

This Quarterly Report on Form 10-Q also contains statistical data, estimates and forecasts that are based on independent industry publications or other publicly available information, as well as other information based on our internal sources. Although we believe that the third-party sources referred to in this Quarterly Report on Form 10-Q are reliable, we have not independently verified the information provided by these third parties. While we are not aware of any misstatements regarding any third-party information presented in this report, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors.

PART I — FINANCIAL INFORMATION**Item 1. Financial Statements.****CAPRICOR THERAPEUTICS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

ASSETS

| | September 30, 2014 (unaudited) | December 31, 2013 |
|--|--------------------------------------|----------------------|
| CURRENT ASSETS | | |
| Cash and cash equivalents | \$9,805,435 | \$1,729,537 |
| Marketable securities | 325,318 | 326,494 |
| Restricted cash | 3,699,660 | 1,401,859 |
| Grant receivable | 259,800 | - |
| Interest receivable | 823 | 187 |
| Prepaid expenses and other current assets | 105,100 | 222,763 |
| TOTAL CURRENT ASSETS | 14,196,136 | 3,680,840 |
| PROPERTY AND EQUIPMENT, at cost | | |
| Furniture and equipment | 38,850 | 38,850 |
| Laboratory equipment | 262,451 | 115,766 |
| Leasehold improvements | 23,744 | - |
| | 325,045 | 154,616 |
| Less accumulated depreciation | (100,499) | (80,429) |
| NET PROPERTY AND EQUIPMENT | 224,546 | 74,187 |
| OTHER ASSETS | | |
| Patents, net of accumulated amortization of \$35,722 and \$32,475 at September 30, 2014 and December 31, 2013, respectively | 288,474 | 227,207 |
| Loan fees, net of accumulated amortization of \$11,757 and \$6,722 at September 30, 2014 and December 31, 2013, respectively | 18,243 | 29,945 |
| In-process research and development, net of accumulated amortization of \$0 at September 30, 2014 and December 31, 2013 | 1,500,000 | 1,500,000 |
| Deposits | 55,320 | 25,728 |

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| | | |
|--|--------------|--------------|
| TOTAL ASSETS | \$16,282,719 | \$5,537,907 |
| LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) | | |
| CURRENT LIABILITIES | | |
| Accounts payable and accrued expenses | \$1,613,066 | \$1,506,509 |
| Accounts payable and accrued expenses, related party | 300,855 | 382,142 |
| Sub-award payable, related party | - | 41,855 |
| Accrued royalties | 111,651 | 122,416 |
| Deferred income, current | 4,166,667 | - |
| TOTAL CURRENT LIABILITIES | 6,192,239 | 2,052,922 |
| LONG-TERM LIABILITIES | | |
| Deferred income, net of current portion | 5,208,332 | - |
| Loan payable | 9,155,857 | 3,961,733 |
| Accrued interest | 198,256 | 58,134 |
| TOTAL LONG-TERM LIABILITIES | 14,562,445 | 4,019,867 |
| TOTAL LIABILITIES | 20,754,684 | 6,072,789 |
| STOCKHOLDERS' EQUITY (DEFICIT) | | |
| Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none issued and outstanding | - | - |
| Common stock, \$0.001 par value, 50,000,000 shares authorized, 11,703,774 and 11,687,747 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively | 11,704 | 11,687 |
| Additional paid-in capital | 15,905,010 | 15,552,946 |
| Accumulated other comprehensive loss | (1,607) | (980) |
| Deficit accumulated during the development stage | (20,387,072) | (16,098,535) |
| TOTAL STOCKHOLDERS' EQUITY (DEFICIT) | (4,471,965) | (534,882) |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) | \$16,282,719 | \$5,537,907 |

See accompanying notes to the unaudited condensed consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****(unaudited)**

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|-------------------------------------|-----------------------|------------------------------------|-----------------------|
| | 2014 | 2013 | 2014 | 2013 |
| INCOME | | | | |
| Collaboration income | \$1,041,667 | \$- | \$3,125,001 | \$- |
| Grant income | 259,800 | 80,432 | 259,800 | 503,233 |
| TOTAL INCOME | 1,301,467 | 80,432 | 3,384,801 | 503,233 |
| OPERATING EXPENSES | | | | |
| Research and development | 1,966,889 | 1,010,544 | 5,203,766 | 3,513,548 |
| General and administrative | 819,683 | 563,948 | 2,332,579 | 1,531,145 |
| TOTAL OPERATING EXPENSES | 2,786,572 | 1,574,492 | 7,536,345 | 5,044,693 |
| LOSS FROM OPERATIONS | (1,485,105) | (1,494,060) | (4,151,544) | (4,541,460) |
| OTHER INCOME (EXPENSE) | | | | |
| Investment income (loss) | 1,210 | (27,822) | 3,129 | (12,205) |
| Interest expense | (60,091) | (23,353) | (140,122) | (33,275) |
| TOTAL OTHER INCOME (EXPENSE) | (58,881) | (51,175) | (136,993) | (45,480) |
| NET LOSS | (1,543,986) | (1,545,235) | (4,288,537) | (4,586,940) |
| OTHER COMPREHENSIVE GAIN (LOSS) | | | | |
| Net unrealized gain (loss) on marketable securities | (733) | 30,141 | (627) | 18,819 |
| COMPREHENSIVE LOSS | \$(1,544,719) | \$(1,515,094) | \$(4,289,164) | \$(4,568,121) |
| Net loss per share, basic and diluted | \$(0.13) | \$(0.15) | \$(0.37) | \$(0.44) |
| Weighted average number of shares, basic and diluted | 11,700,136 | 10,351,294 | 11,694,004 | 10,351,294 |

See accompanying notes to the unaudited condensed consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.

**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(DEFICIT)**

(unaudited)

| | COMMON STOCK | | | | | |
|------------------------------|--------------|-----------|----------------------------|--------------------------|--|--------------------------------------|
| | SHARES | AMOUNT | ADDITIONAL PAID-IN CAPITAL | OTHER COMPREHENSIVE LOSS | DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE | TOTAL STOCKHOLDERS' EQUITY (DEFICIT) |
| Balance at December 31, 2013 | 11,687,747 | \$ 11,687 | \$ 15,552,946 | \$ (980 |) \$ (16,098,535 |) |