CAPRICOR THERAPEUTICS, INC.
Form 10-Q
August 15, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

for the quarterly period ended June 30, 2016

or

o **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 90211

(Address of principal executive offices including 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. þ 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 þ No o

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 þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ¨ Yes þ 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 August 12, 2016, there were 17,954,398 shares of the registrant's common stock, par value $0.001 per share, issued and outstanding.

INDEX TO QUARTERLY REPORT ON FORM 10-Q

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, investigational new drug filings and 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 ability to compete against other companies and research institutions;
- our ability to expand our operations internationally;
- 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, if any.

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

	June 30, 2016 (unaudited)	December 31, 2015
CURRENT ASSETS		
Cash and cash equivalents	$8,851,129	$5,568,306
Marketable securities	2,499,975	7,999,010
Grant receivable	218,361	211,938
Prepaid expenses and other current assets	239,263	210,603
TOTAL CURRENT ASSETS	11,808,728	13,989,857
PROPERTY AND EQUIPMENT, net	355,284	318,566
OTHER ASSETS		
Intangible assets, net of accumulated amortization of $123,054 and $98,679, respectively	166,628	191,003
In-process research and development, net of accumulated amortization of $0	1,500,000	1,500,000
Other assets	61,556	70,146
TOTAL ASSETS	$13,892,196	$16,069,572
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$2,923,600	$2,530,500
Accounts payable and accrued expenses, related party	546,725	352,334
Deferred revenue, current	2,734,376	3,645,834
TOTAL CURRENT LIABILITIES	6,204,701	6,528,668
LONG-TERM LIABILITIES		
Deferred revenue, net of current portion	-	911,458
Loan payable	12,155,857	9,155,857
Accrued interest	647,815	505,363

TOTAL LONG-TERM LIABILITIES	12,803,672	10,572,678
TOTAL LIABILITIES	19,008,373	17,101,346
COMMITMENTS AND CONTINGENCIES (NOTE 6)		
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, 17,952,323 and 16,254,985 shares issued and outstanding, respectively	17,952	16,255
Additional paid-in capital	38,988,747	34,115,052
Accumulated other comprehensive income	4,778	9,385
Accumulated deficit	(44,127,654)	(35,172,466)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(5,116,177)	(1,031,774)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$13,892,196	$16,069,572

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 June 30,		Six months ended June 30,	
	2016	2015	2016	2015
INCOME				
Collaboration income	$911,458	$911,458	$1,822,916	$1,953,125
Grant income	218,361	380,008	521,992	1,126,243
TOTAL INCOME	1,129,819	1,291,466	2,344,908	3,079,368
OPERATING EXPENSES				
Research and development	4,307,948	3,426,803	8,649,067	7,233,891
General and administrative	1,434,259	926,279	2,518,955	2,321,819
TOTAL OPERATING EXPENSES	5,742,207	4,353,082	11,168,022	9,555,710
LOSS FROM OPERATIONS	(4,612,388)	(3,061,616)	(8,823,114)	(6,476,342)
OTHER INCOME (EXPENSE)				
Investment income	427	156	10,937	431
Interest expense	(76,887)	(61,681)	(143,011)	(123,362)
TOTAL OTHER INCOME (EXPENSE)	(76,460)	(61,525)	(132,074)	(122,931)
NET LOSS	(4,688,848)	(3,123,141)	(8,955,188)	(6,599,273)
OTHER COMPREHENSIVE GAIN (LOSS)				
Net unrealized gain (loss) on marketable securities	1,551	10,475	(4,607)	6,535
COMPREHENSIVE LOSS	$(4,687,297)	$(3,112,666)	$(8,959,795)	$(6,592,738)
Net loss per share, basic and diluted	$(0.26)	$(0.19)	$(0.52)	$(0.42)
Weighted average number of shares, basic and diluted	17,952,323	16,222,754	17,244,912	15,549,988

See accompanying notes to the unaudited condensed consolidated financial statements.

5

CAPRICOR THERAPEUTICS, INC.

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

(unaudited)

	COMMON STOCK					
	SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME (LOSS)	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY (DEFICIT)
Balance at December 31, 2015	16,254,985	$ 16,255	$ 34,115,052	$ 9,385	$ (35,172,466)	$ (1,031,774)
Issuance of common stock, net of fees	1,692,151	1,692	3,928,103	-	-	3,929,795
Stock-based compensation	-	-	944,611	-	-	944,611
Unrealized loss on marketable securities	-	-	-	(4,607)	-	(4,607)
Stock options exercised	5,187	5	981	-	-	986
Net loss	-	-	-	-	(8,955,188)	(8,955,188)
Balance at June 30, 2016	17,952,323	$ 17,952	$ 38,988,747	$ 4,778	$ (44,127,654)	$ (5,116,177)

See accompanying notes to the unaudited condensed consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Six months ended June 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(8,955,188)	$(6,599,273)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	65,097	51,004
Stock-based compensation	944,611	915,051
Change in assets - (increase) decrease:		
Restricted cash	-	2,377,442
Receivables	(6,423)	(19,775)
Prepaid expenses and other current assets	(28,660)	104,799
Other assets	8,590	(14,135)
Change in liabilities - increase (decrease):		
Accounts payable and accrued expenses	393,100	979,594
Accounts payable and accrued expenses, related party	194,391	105,009
Accrued interest	142,452	123,362
Deferred revenue	(1,822,916)	(1,953,125)
NET CASH USED IN OPERATING ACTIVITIES	(9,064,946)	(3,930,047)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(2,505,572)	(15,487,830)
Proceeds from sales and maturities of marketable securities	8,000,000	-
Purchases of property and equipment	(75,671)	(50,760)
Payments for leasehold improvements	(1,769)	(9,473)
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	5,416,988	(15,548,063)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	3,929,795	16,446,218
Proceeds from loan payable	3,000,000	-
Proceeds from stock awards, warrants, and options	986	35,387
NET CASH PROVIDED BY FINANCING ACTIVITIES	6,930,781	16,481,605
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,282,823	(2,996,505)
Cash and cash equivalents balance at beginning of period	5,568,306	8,034,765

Cash and cash equivalents balance at end of period	$8,851,129	$5,038,260
SUPPLEMENTAL DISCLOSURES:		
Interest paid in cash	$1,343	$2,685
Income taxes paid in cash	$-	$-

See accompanying notes to the unaudited condensed consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.

Notes to CONDENSED CONSOLIDATED financial statements

(unaudited)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

The mission of Capricor Therapeutics, Inc., a Delaware corporation (referred to herein as "Capricor Therapeutics" or the "Company"), is to improve the treatment of diseases by commercializing innovative therapies, focusing on cardiovascular diseases as well as exploring other indications. Capricor, Inc., a privately-held company and a wholly-owned subsidiary of Capricor Therapeutics (referred to herein as "Capricor"), was founded in 2005 as a Delaware corporation based on the innovative work of its founder, Eduardo Marbán, M.D., Ph.D. After completion of a merger between Capricor and a subsidiary of Nile Therapeutics, Inc., a Delaware corporation ("Nile"), on November 20, 2013, Capricor became a wholly-owned subsidiary of Nile and Nile formally changed its name to Capricor Therapeutics, Inc. Capricor Therapeutics, together with its subsidiary, Capricor, currently has six drug candidates in various stages of development.

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements for Capricor Therapeutics and its wholly-owned subsidiary have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") and with the instructions to Form 10-Q and, therefore, do not include all disclosures necessary for a complete presentation of financial position, results of operations and cash flows in conformity with U.S. GAAP. In the Company's opinion, all adjustments, consisting of normal and recurring adjustments, considered necessary for a fair presentation have been included. The accompanying financial information should be read in conjunction with the financial statements and the notes thereto in the Company's most recent Annual Report on Form 10-K, as filed with the Securities and Exchange Commission on March 30, 2016, from which the December 31, 2015 consolidated balance sheet has been derived. Interim results are not necessarily indicative of the results that may be expected for the year ending December 31, 2016.

Basis of Consolidation

Our condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All intercompany transactions have been eliminated in consolidation.

Liquidity

The Company has historically financed its research and development activities as well as operational expenses from equity financings, government grants, a payment from Janssen Biotech, Inc. ("Janssen") pursuant to a Collaboration Agreement with Janssen and a loan award from the California Institute for Regenerative Medicine ("CIRM").

Cash, cash equivalents and marketable securities as of June 30, 2016 were approximately $11.4 million, compared to $13.6 million as of December 31, 2015. In March 2016, the Company entered into a Subscription Agreement with certain investors pursuant to which the Company issued an aggregate of 1,692,151 shares of its common stock at a price per share of $2.40 for an aggregate purchase price of approximately $4.1 million. Pursuant to the Subscription Agreement, the Company also issued to the investors warrants to purchase up to an aggregate of 846,073 shares of its common stock. Each warrant has an exercise price of $4.50 per share, will initially be exercisable on September 17, 2016, and will expire on March 16, 2019. Additionally, under the terms of the Company's ALLSTAR Loan Award with CIRM (see Note 2 – "Loan Payable"), Capricor received $3.0 million in additional disbursements in the six months ended June 30, 2016.

Furthermore, in June 2016, Capricor entered into a Grant Award with CIRM in the amount of approximately $3.4 million (the "CIRM Award") to fund, in part, Capricor's Phase I/II HOPE-Duchenne clinical trial. Pursuant to the terms of the CIRM Award, the disbursements are tied to the achievement of specified operational milestones. In addition, the terms of the CIRM Award include a co-funding requirement pursuant to which Capricor is required to spend a minimum of approximately $2.3 million of its own capital to fund the HOPE-Duchenne clinical trial. In July 2016, Capricor received the first disbursement of $2.0 million under the terms of the CIRM Award (see Note 6 – "Commitments and Contingencies"). The Company's principal uses of cash are for research and development expenses, general and administrative expenses, capital expenditures and other working capital requirements.

CAPRICOR THERAPEUTICS, INC.

Notes to CONDENSED CONSOLIDATED financial statements

(unaudited)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

The Company's future expenditures and capital requirements may be substantial and will depend on many factors, including, but not limited to, the following:

- the timing and costs associated with the manufacturing of its product candidates;
- the timing and costs associated with commercialization of its product candidates;
- the timing and costs associated with its clinical trials and preclinical studies;
- the number and scope of its research programs; and
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights.

The Company's cash requirements are expected to continue to increase as it advances its research, development and commercialization programs, and the Company expects to seek additional financing primarily from, but not limited to, the sale and issuance of equity or debt securities, the licensing or sale of its technology and from government grants. The Company cannot provide assurances that financing will be available when and as needed or that, if available, financing will be available on favorable or acceptable terms or at all. If the Company is unable to obtain additional financing when and if required, it would have a material adverse effect on the Company's business and results of operations and the Company could be required to reduce expenses and curtail operations. To the extent the Company issues additional equity securities, its existing stockholders could experience substantial dilution.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. The most sensitive estimates relate to the period over which collaboration revenue is recognized and the assumptions used to estimate stock-based compensation expense. Management uses its historical records and knowledge of its business in making these estimates. Accordingly, actual results may differ from these estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents.

Restricted Cash

Restricted cash represents funds received under Capricor's Loan Agreement with CIRM (see Note 2 – "Loan Payable"), which are to be allocated to the ALLSTAR clinical trial research costs as incurred. Generally, a reduction of restricted cash occurs when the Company deems certain costs are attributable to the ALLSTAR clinical trial. As of June 30, 2016 and December 31, 2015, the Company had a restricted cash balance of zero.

Marketable Securities

The Company determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company's marketable securities are considered as available-for-sale and carried at estimated fair values. Realized gains and losses on the sale of debt and equity securities are determined using the specific identification method. Unrealized gains and losses on available-for-sale securities are excluded from net income and reported in accumulated other comprehensive income (loss) as a separate component of stockholders' equity.

Property and Equipment

Property and equipment are stated at cost. Repairs and maintenance costs are expensed in the period incurred. Depreciation is computed using the straight-line method over the related estimated useful life of the asset, which such estimated useful lives range from five to seven years. Leasehold improvements are depreciated on a straight-line basis over the shorter of the useful life of the asset or the lease term. Depreciation was approximately $40,722 and $26,629 for the six months ended June 30, 2016 and 2015, respectively.

CAPRICOR THERAPEUTICS, INC.

Notes to CONDENSED CONSOLIDATED financial statements

(unaudited)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Property and equipment consisted of the following as of June 30, 2016 and December 31, 2015:

	June 30, 2016	December 31, 2015
Furniture and fixtures	$59,128	$59,128
Laboratory equipment	463,543	387,872
Leasehold improvements	47,043	45,274
	569,714	492,274
Less accumulated depreciation	(214,430)	(173,708)
Property and equipment, net	$355,284	$318,566

Intangible Assets

Amounts attributable to intellectual property consist primarily of the costs associated with the acquisition of certain technologies, patents, pending patents and related intangible assets with respect to research and development activities. Intellectual property assets are stated at cost and are amortized on a straight-line basis over the respective estimated useful lives of the assets ranging from five to fifteen years. Also, the Company recorded capitalized loan fees as a component of intangible assets on the consolidated balance sheet (see Note 2 – “Loan Payable”). Total amortization expense was approximately $24,375 for each of the six month periods ended June 30, 2016 and 2015. A summary of future amortization expense as of June 2016 is as follows:

Years ended	Amortization Expense
2016 (6 months)	$ 24,375
2017	48,749
2018	43,732
2019	43,277

2020	4,330
Thereafter	2,165

As a result of the merger in 2013 between Capricor and Nile, the Company recorded $1.5 million as in-process research and development in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 805, *Business Combinations*. The in-process research and development asset is subject to impairment testing until completion or abandonment of research and development efforts associated with the project. Upon successful completion of the project, the Company will make a determination as to the then remaining useful life of the intangible asset and begin amortization.

The Company reviews intangible assets at least annually for possible impairment. Intangible assets are reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying value. As of June 30, 2016, the Company deemed the assets to not be impaired and did not begin amortizing the in-process research and development.

Government Research Grants

Generally, government research grants that provide funding for research and development activities are recognized as income when the related expenses are incurred, as applicable. In August 2013, Capricor was approved for a Phase IIB bridge grant through the National Institutes of Health ("NIH") Small Business Innovation Research ("SBIR") program for continued development of its CAP-1002 product candidate. Under the terms of the NIH grant, disbursements were made to Capricor over a period of approximately three years, in an aggregate amount of approximately $2.9 million, subject to annual and quarterly reporting requirements. As of June 30, 2016, the full award of $2.9 million had been incurred under the terms of the NIH grant award.

CAPRICOR THERAPEUTICS, INC.

Notes to CONDENSED CONSOLIDATED financial statements

(unaudited)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Income from Collaboration Agreement

Revenue from nonrefundable, up-front license or technology access payments under license and collaborative arrangements that are not dependent on any future performance by the Company is recognized when such amounts are earned. If the Company has continuing obligations to perform under the arrangement, such fees are recognized over the estimated period of the continuing performance obligation.

The Company accounts for multiple element arrangements, such as license and development agreements in which a customer may purchase several deliverables, in accordance with FASB ASC Subtopic 605-25, *Multiple Element Arrangements*. For new or materially amended multiple element arrangements, the Company identifies the deliverables at the inception of the arrangement and each deliverable within a multiple deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in the Company's control. The Company allocates revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, the Company determines the selling price for each deliverable using vendor-specific objective evidence ("VSOE") of selling price, if it exists, or third-party evidence ("TPE") of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, then the Company uses the best estimated selling price for that deliverable. Revenue allocated to each element is then recognized based on when the basic four revenue recognition criteria are met for each element.

The Company determined that the deliverables under its Collaboration Agreement with Janssen (see Note 7 – "License Agreements") did not meet the criteria to be considered separate accounting units for the purposes of revenue recognition. As a result, the Company recognizes revenue from non-refundable, upfront fees ratably over the term of its performance under the agreement with Janssen. The upfront payments received, pending recognition as revenue, are recorded as deferred revenue and are classified as a short-term or long-term liability on the condensed consolidated balance sheets of the Company and amortized over the estimated period of performance. The Company periodically reviews the estimated performance period of its contract based on the estimated progress of its project.

Loan Payable

The Company accounts for the funds advanced under its Loan Agreement with CIRM (see Note 2 – "Loan Payable") as a loan payable as the eventual repayment of the loan proceeds or forgiveness of the loan is contingent upon certain future milestones being met and other conditions. As the likelihood of whether or not the Company will ever achieve these milestones or satisfy these conditions cannot be reasonably predicted at the time of the filing of this Quarterly Report on Form 10-Q, the Company records these amounts as a loan payable.

Rent

Rent expense for the Company's leases, which generally have escalating rental amounts over the term of the lease, is recorded on a straight-line basis over the lease term. The difference between the rent expense and rent paid has been recorded as deferred rent in the consolidated balance sheet accounts payable and accrued expenses, related party. Rent is amortized on a straight-line basis over the term of the applicable lease, without consideration of renewal options.

Research and Development

Costs relating to the design and development of new products are expensed as research and development as incurred in accordance with FASB ASC 730-10, *Research and Development*. Research and development costs amounted to approximately $4.3 million and $3.4 million for the three months ended June 30, 2016 and 2015, respectively, and $8.6 million and $7.2 million for the six months ended June 30, 2016 and 2015, respectively.

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders' equity during the period except those resulting from investments by, or distributions to, stockholders. The Company's comprehensive loss was approximately $4.7 million and $3.1 million for the three months ended June 30, 2016 and 2015, respectively, and $9.0 million and $6.6 million for the six months ended June 30, 2016 and 2015, respectively. The Company's other comprehensive income (loss) is related to a net unrealized gain (loss) on marketable securities. For the three months ended June 30, 2016 and 2015, the Company's other comprehensive gain was $1,551 and $10,475, respectively. For the six months ended June 30, 2016 and 2015, the Company's other comprehensive gain (loss) was $(4,607) and $6,535, respectively.

CAPRICOR THERAPEUTICS, INC.

Notes to CONDENSED CONSOLIDATED financial statements

(unaudited)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Stock-Based Compensation

The Company accounts for stock-based employee compensation arrangements in accordance with guidance issued by the FASB, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, consultants, and directors based on estimated fair values.

The Company estimates the fair value of stock-based compensation awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the Company's statements of operations.

The Company estimates the fair value of stock-based compensation awards using the Black-Scholes model. This model requires the Company to estimate the expected volatility and value of its common stock and the expected term of the stock options, all of which are highly complex and subjective variables. The variables take into consideration, among other things, actual and projected stock option exercise behavior. The Company calculates an average of historical volatility of similar companies as a basis for its expected volatility. Expected term is computed using the simplified method provided within Securities and Exchange Commission ("SEC") Staff Accounting Bulletin No. 110. The Company has selected a risk-free rate based on the implied yield available on U.S. Treasury securities with a maturity equivalent to the expected term of the options.

Basic and Diluted Loss per Share

Basic loss per share is computed using the weighted-average number of common shares outstanding during the period. Diluted loss per share is computed using the weighted-average number of common shares and dilutive potential common shares outstanding during the period. Dilutive potential common shares, which primarily consist of stock options issued to employees, consultants and directors as well as warrants issued to third parties, have been excluded from the diluted loss per share calculation because their effect is anti-dilutive.

For the three months ended June 30, 2016 and 2015, warrants and options to purchase 7,732,632 and 6,143,299 shares of common stock, respectively, have been excluded from the computation of potentially dilutive securities. For the six months ended June 30, 2016 and 2015, warrants and options to purchase 7,732,632 and 6,143,299 shares of common stock, respectively, have been excluded from the computation of potentially dilutive securities.

Fair Value Measurements

Assets and liabilities recorded at fair value in the balance sheet are categorized based upon the level of judgment associated with the inputs used to measure their fair value. The categories are as follows:

Level Input:	Input Definition:
Level I	Inputs are unadjusted, quoted prices for identical assets or liabilities in active markets at the measurement date.
Level II	Inputs, other than quoted prices included in Level I, that are observable for the asset or liability through corroboration with market data at the measurement date.
Level III	Unobservable inputs that reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date.

The following table summarizes fair value measurements by level at June 30, 2016 for assets and liabilities measured at fair value on a recurring basis:

	June 30, 2016			
	Level I	Level II	Level III	Total
Marketable securities'	$2,499,975	$-	$-	$2,499,975

12

CAPRICOR THERAPEUTICS, INC.

Notes to CONDENSED CONSOLIDATED financial statements

(unaudited)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Carrying amounts reported in the balance sheet of cash and cash equivalents, grants receivable, accounts payable and accrued expenses approximate fair value due to their relatively short maturity. The carrying amounts of the Company's marketable securities are based on market quotations from national exchanges at the balance sheet date. Interest and dividend income are recognized separately on the income statement based on classifications provided by the brokerage firm holding the investments. The fair value of borrowings is not considered to be significantly different than its carrying amount because the stated rates for such debt reflect current market rates and conditions.

Warrant Liability

The Company accounts for some of its warrants issued in accordance with the guidance on Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, which provides that the Company must classify the warrant instrument as a liability at its fair value and adjust the instrument to fair value at each reporting period. The fair value of warrants is estimated by management using the Black-Scholes option-pricing model. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized as a component of other income or expense. Management has determined the value of the warrant liability to be insignificant at June 30, 2016, and no such liability has been reflected on the balance sheet.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"). ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current U.S. GAAP and replace it with a principle-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for reporting periods beginning after December 15, 2017, and early adoption is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The

Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Topic 915): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"), which states that in connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). ASU 2014-15 is effective for the annual period ending after December 15, 2016 and for annual and interim periods thereafter. Early adoption is permitted. The adoption of this update is not expected to have a material effect on the Company's financial statements.

In February 2015, the FASB issued ASU 2015-02, *Consolidation (Topic 810): Amendments to the Consolidation Analysis* ("ASU 2015-02"). This standard modifies existing consolidation guidance for reporting organizations that are required to evaluate whether they should consolidate certain legal entities. ASU 2015-02 is effective for fiscal years and interim periods within those years beginning after December 15, 2015, and requires either a retrospective or a modified retrospective approach to adoption. Early adoption is permitted. The Company adopted this standard effective December 31, 2015.

In April 2015, the FASB issued ASU 2015-03, *Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-03"). This update changes the presentation of debt issuance costs in the balance sheet. ASU 2015-03 requires debt issuance costs related to a recognized debt obligation to be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability rather than being presented as an asset. Amortization of debt issuance costs will continue to be reported as interest expense. In August 2015, the FASB issued ASU 2015-15, *Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of Credit Arrangements* ("ASU 2015-15"). ASU 2015-15 clarified guidance in ASU 2015-03 by providing that the SEC staff would not object to a company presenting debt issuance costs related to a line-of-credit arrangement on the balance sheet as a deferred asset, regardless of whether there were any outstanding borrowings at period-end. This update is effective for annual and interim periods beginning after December 15, 2015, which required the Company to adopt these provisions in the first quarter of 2016. This update was applied on a retrospective basis, wherein the balance sheet of each period presented was adjusted to reflect the effects of applying the new guidance.

CAPRICOR THERAPEUTICS, INC.

Notes to CONDENSED CONSOLIDATED financial statements

(unaudited)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which supersedes existing guidance on accounting for leases in *Leases (Topic 840)* and generally requires all leases to be recognized in the consolidated balance sheet. ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018; early adoption is permitted. The provisions of ASU 2016-02 are to be applied using a modified retrospective approach. The Company is currently evaluating the impact of the adoption of this standard on its condensed consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which outlines new provisions intended to simplify various aspects related to accounting for share-based payments and their presentation in the financial statements. The standard is effective for the Company beginning December 15, 2016 and for interim periods within those annual periods. Early adoption is permitted. The Company is evaluating the impact of the adoption of this guidance on its financial statements.

In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers (Topic 606)*, which amends certain aspects of the FASB's and International Accounting Standards Board's new revenue standard, ASU 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"). The standard should be adopted concurrently with the adoption of ASU 2014-09, which is effective for annual and interim periods beginning after December 15, 2017. Early adoption is permitted. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the SEC, did not or are not believed by management to have a material impact on the Company's present or future condensed consolidated financial statement presentation or disclosures. For a more detailed listing of the Company's significant accounting policies, see Note 1 – "Organization and Summary of Significant Accounting Policies," of the notes to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on March 30, 2016.

2. LOAN PAYABLE

On February 5, 2013, Capricor entered into a Loan Agreement with CIRM (the "CIRM Loan Agreement"), pursuant to which CIRM agreed to disburse $19,782,136 to Capricor over a period of approximately three and one-half years to support Phase II of Capricor's ALLSTAR clinical trial. On May 12, 2016, the Company and CIRM entered into an amendment to the CIRM Loan Agreement (the "CIRM Loan Amendment") pursuant to which the parties agreed, among other things, upon a schedule for future disbursements of the proceeds of the loan amount based upon the achievement of specified operational milestones. As a result of the CIRM Loan Amendment and because the Company is decreasing the number of patients to be enrolled in the ALLSTAR clinical trial, it is likely that the Company will not need to take down the full amount available for disbursement under the CIRM Loan Agreement and that certain operational milestones tied to patient enrollment will not be met. The Company believes that the amount that will ultimately be disbursed will be approximately 70-75% of the total amount specified in the CIRM Loan Agreement, thus reducing the total amount of debt incurred thereunder.

Under the CIRM Loan Agreement, Capricor is required to repay the CIRM loan with interest at the end of the loan period. The loan also provides for the payment of a risk premium whereby Capricor is required to pay CIRM a premium of up to 500% of the loan amount upon the achievement of certain revenue thresholds. The loan has a term of five years and is extendable annually up to ten years at Capricor's option if certain conditions are met. The interest rate for the initial term is set at the one-year LIBOR rate plus 2% ("base rate"), compounded annually, and becomes due at the end of the fifth year. After the fifth year, if the term of the loan is extended and if certain conditions are met, the interest rate will increase by 1% over the base rate each sequential year thereafter, with a maximum increase of 5% over the base rate in the tenth year. CIRM has the right to cease disbursements if a no-go milestone occurs or certain other conditions are not met. The Company is also required to meet certain progress milestones set forth in the CIRM Notice of Loan Award with respect to the progress of the ALLSTAR clinical trial and manufacturing of the product. There is no assurance that CIRM will continue the disbursement of funds.

CAPRICOR THERAPEUTICS, INC.

Notes to CONDENSED CONSOLIDATED financial statements

(unaudited)

2. LOAN PAYABLE (continued)