

CAPRICOR THERAPEUTICS, INC.  
Form 10-Q  
May 13, 2015

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

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**FORM 10-Q**

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

**For the quarterly period ended March 31, 2015**

**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**

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**CAPRICOR THERAPEUTICS, INC.**

**(Exact Name Of Registrant As Specified In Its Charter)**

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**Delaware** **88-0363465**  
**(State or other jurisdiction of incorporation or organization)** **(I.R.S. Employer Identification No.)**

**8840 Wilshire Blvd., 2<sup>nd</sup> Floor, Beverly Hills, California 90211**

**(Address of principal executive offices including zip code)**

**(310) 358-3200**

**(Registrant's telephone number, including area code)**

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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 May 11, 2015 there were 16,223,281 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, investigational new drug 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

	March 31, 2015 (unaudited)	December 31, 2014
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$6,939,220	\$8,034,765
Marketable securities	15,483,890	-
Restricted cash	2,047,930	2,977,024
Grant receivable	746,235	360,233
Prepaid expenses and other current assets	202,984	235,523
<b>TOTAL CURRENT ASSETS</b>	<b>25,420,259</b>	<b>11,607,545</b>
<b>PROPERTY AND EQUIPMENT, net</b>	<b>253,768</b>	<b>229,455</b>
<b>OTHER ASSETS</b>		
Intangible assets, net of accumulated amortization of \$62,118 and \$49,930, respectively	227,565	239,752
In-process research and development, net of accumulated amortization of \$0	1,500,000	1,500,000
Other assets	69,455	55,320
<b>TOTAL ASSETS</b>	<b>\$27,471,047</b>	<b>\$13,632,072</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued expenses	\$2,745,935	\$1,699,254
Accounts payable and accrued expenses, related party	632,699	433,712
Deferred revenue, current	4,166,667	4,166,667
<b>TOTAL CURRENT LIABILITIES</b>	<b>7,545,301</b>	<b>6,299,633</b>
<b>LONG-TERM LIABILITIES</b>		
Deferred revenue, net of current portion	3,124,999	4,166,666

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Loan payable	9,155,857	9,155,857
Accrued interest	320,346	258,639
<b>TOTAL LONG-TERM LIABILITIES</b>	<b>12,601,202</b>	<b>13,581,162</b>
<b>TOTAL LIABILITIES</b>	<b>20,146,503</b>	<b>19,880,795</b>
<b>STOCKHOLDERS' EQUITY (DEFICIT)</b>		
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, 16,221,985 and 11,707,051 shares issued and outstanding, respectively	16,222	11,707
Additional paid-in capital	33,103,520	16,054,697
Accumulated other comprehensive loss	(3,940 )	-
Accumulated deficit	(25,791,258)	(22,315,127)
<b>TOTAL STOCKHOLDERS' EQUITY (DEFICIT)</b>	<b>7,324,544</b>	<b>(6,248,723 )</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>	<b>\$27,471,047</b>	<b>\$13,632,072</b>

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 March 31,	
	2015	2014
<b>INCOME</b>		
Collaboration income	\$1,041,667	\$1,041,667
Grant income	746,235	-
<b>TOTAL INCOME</b>	<b>1,787,902</b>	<b>1,041,667</b>
<b>OPERATING EXPENSES</b>		
Research and development	3,807,087	1,374,757
General and administrative	1,395,540	852,347
<b>TOTAL OPERATING EXPENSES</b>	<b>5,202,627</b>	<b>2,227,104</b>
<b>LOSS FROM OPERATIONS</b>	<b>(3,414,725 )</b>	<b>(1,185,437 )</b>
<b>OTHER INCOME (EXPENSE)</b>		
Investment income	275	153
Interest expense	(61,681 )	(25,327 )
<b>TOTAL OTHER INCOME (EXPENSE)</b>	<b>(61,406 )</b>	<b>(25,174 )</b>
<b>NET LOSS</b>	<b>(3,476,131 )</b>	<b>(1,210,611 )</b>
<b>OTHER COMPREHENSIVE GAIN (LOSS)</b>		
Net unrealized gain (loss) on marketable securities	(3,940 )	576
<b>COMPREHENSIVE LOSS</b>	<b>\$(3,480,071 )</b>	<b>\$(1,210,035 )</b>
Net loss per share, basic and diluted	\$(0.23 )	\$(0.10 )
Weighted average number of shares, basic and diluted	14,869,746	11,689,441

See accompanying notes to the unaudited condensed consolidated financial statements.



**CAPRICOR THERAPEUTICS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
(DEFICIT)****(unaudited)**

	<b>COMMON STOCK</b>			<b>OTHER</b>	<b>ACCUMULATED</b>	<b>TOTAL</b>
	<b>SHARES</b>	<b>AMOUNT</b>	<b>ADDITIONAL PAID-IN CAPITAL</b>	<b>COMPREHENSIVE INCOME (LOSS)</b>	<b>DEFICIT</b>	<b>STOCKHOLDERS' EQUITY (DEFICIT)</b>
Balance at December 31, 2014	11,707,051	\$ 11,707	\$ 16,054,697	\$ -	\$ (22,315,127 )	\$ (6,248,723 )
Issuance of common stock, net of fees	4,497,867	4,498	16,441,720	-	-	16,446,218
Stock-based compensation	1,666	2	572,119	-	-	572,121
Unrealized loss on marketable securities	-	-	-	(3,940 )	-	(3,940 )
Warrants exercised	15,401	15	34,984	-	-	34,999
Net loss	-	-	-	-	(3,476,131 )	(3,476,131 )
Balance at March 31, 2015	16,221,985	\$ 16,222	\$ 33,103,520	\$ (3,940 )	\$ (25,791,258 )	\$ 7,324,544

See accompanying notes to the unaudited condensed consolidated financial statements.

**CAPRICOR THERAPEUTICS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(unaudited)**

	Three months ended March 31,	
	2015	2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(3,476,131 )	\$(1,210,611 )
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	24,802	6,465
Stock-based compensation	572,121	84,544
Change in assets - (increase) decrease:		
Restricted cash	929,094	846,627
Grants receivable	(386,002 )	-
Prepaid expenses and other current assets	32,539	52,614
Other assets	(14,135 )	-
Change in liabilities - increase (decrease):		
Accounts payable and accrued expenses	1,046,681	22,049
Accounts payable and accrued expenses, related party	198,987	57,646
Accrued interest	61,707	25,327
Deferred revenue	(1,041,667 )	11,458,333
<b>NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES</b>	<b>(2,052,004 )</b>	<b>11,342,994</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of marketable securities	(15,487,830)	(226,998 )
Proceeds from sales and maturities of marketable securities	-	227,842
Purchases of property and equipment	(27,455 )	(92,901 )
Payments for leasehold improvements	(9,473 )	-
Other investing activities, net	-	(2,257 )
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>(15,524,758)</b>	<b>(94,314 )</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Net proceeds from sale of common stock	16,446,218	-
Proceeds from stock awards, warrants, and options	34,999	933
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>16,481,217</b>	<b>933</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>(1,095,545 )</b>	<b>11,249,613</b>
Cash and cash equivalents balance at beginning of period	8,034,765	1,729,537

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Cash and cash equivalents balance at end of period	\$6,939,220	\$12,979,150
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SUPPLEMENTAL DISCLOSURES:

Interest paid in cash	\$-	\$-
Income taxes paid in cash	\$-	\$-

See accompanying notes to the unaudited condensed consolidated financial statements.

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**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, with a primary focus on cardiovascular diseases. 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 16, 2015, from which the December 31, 2014 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, 2015.

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”) and a loan award from the California Institute for Regenerative Medicine (“CIRM”). Cash resources consisting of cash, cash equivalents and marketable securities as of March 31, 2015 were approximately \$22.4 million, compared to \$8.0 million as of December 31, 2014. On January 7, 2014, Capricor received \$12.5 million from Janssen pursuant to the terms of the Collaboration Agreement and Exclusive License Option entered into on December 27, 2013 by and between the Company and Janssen.

In January 2015, the Company entered into a Share Purchase Agreement with select investors, pursuant to which the Company issued an aggregate of 2,839,045 shares of its common stock at a price per share of \$3.523 for an aggregate purchase price of approximately \$10,000,000.

In February 2015, the Company entered into a Share Purchase Agreement with select investors, pursuant to which the Company issued an aggregate of 1,658,822 shares of its common stock at a price per share of \$4.25 for an aggregate purchase price of approximately \$7,050,000.

The Company will need substantial additional financing in the future until it can achieve profitability, if ever. The Company’s continued operations will depend on its ability to raise additional funds through various potential sources, such as equity and debt financing, or to license its compounds to another pharmaceutical company. The Company will continue to fund operations from cash on hand and through sources of capital similar to those previously described.

### 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. Management uses its historical records and knowledge of its business in making these estimates. Accordingly, actual results may differ from these estimates.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

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

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

As of March 31, 2015 and December 31, 2014, restricted cash represented 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.

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.

### 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 being 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 condensed consolidated balance sheet (see Note 2 – “Loan Payable”). Total amortization expense was approximately \$12,187 and \$2,916 for the three months ended March 31, 2015 and 2014, respectively. Future amortization expense for the next five years is estimated to be approximately \$49,000 per year.

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 goodwill and indefinite-lived intangible assets at least annually for possible impairment. Goodwill and indefinite-lived 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 March 31, 2015, the Company deemed the assets to not be impaired and did not amortize 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.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

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

Income from Collaborative 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 the deliverables under its collaborative arrangement 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 recognized 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 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 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 this time, the Company records these amounts as a loan payable.

### 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 \$3.8 million and \$1.4 million for the three months ended March 31, 2015 and 2014, 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 \$3.5 million and \$1.2 million for the three months ended March 31, 2015 and 2014, respectively. The Company’s other comprehensive income (loss) is related to a net unrealized gain (loss) on marketable securities. For the three months ended March 31, 2015 and 2014, the Company’s other comprehensive gain (loss) was \$(3,940) and \$576, respectively.

### 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 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.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

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

For the three months ended March 31, 2015 and 2014, warrants and options to purchase 6,098,330 and 5,041,281 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 March 31, 2015 for assets and liabilities measured at fair value on a recurring basis:

	March 31, 2015			
	Level I	Level II	Level III	Total
Marketable securities	\$15,483,890	\$ -	\$ -	\$15,483,890

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 March 31, 2015, 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 generally accepted accounting principles in the United States of America ("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, 2016, 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. We are currently evaluating the effect that ASU 2014-09 will have on our condensed consolidated financial statement presentation or disclosures.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission, 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, 2014, as filed with the Securities and Exchange Commission on March 16, 2015.



**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**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.

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 not discontinue the disbursement of funds. Capricor is in ongoing discussions with CIRM regarding the timing of the disbursements of funds in accordance with enrollment.

Under the terms of the CIRM Loan Agreement, CIRM deducted \$36,667 from the initial disbursement to cover its costs in conducting financial due diligence on Capricor. According to the original CIRM Loan Agreement, CIRM intended to also deduct approximately \$16,667 from each disbursement made in the second and third year of the loan period to cover its costs of continuing due diligence according to the payment disbursement schedule. However, in June 2014, the CIRM Loan Agreement was amended to adjust the due diligence costs which can be deducted from the disbursements. CIRM refunded approximately \$6,667 to Capricor, which amount CIRM had previously withheld, and CIRM will not be permitted to withhold additional funds from the indirect costs portion of Capricor’s future disbursements. So long as Capricor is not in default under the terms of the CIRM Loan Agreement, the loan may be forgiven during the term of the project period if Capricor abandons the trial due to the occurrence of a no-go milestone. After the end of the project period, the loan may also be forgiven if Capricor elects to abandon the project under certain circumstances. Under the terms of the CIRM Loan Agreement, Capricor is required to meet certain financial milestones by demonstrating to CIRM prior to each disbursement of loan proceeds that it has sufficient funds available to cover all costs and expenses anticipated to be required to continue Phase II of the ALLSTAR trial for at least the following 12-month period, less the costs budgeted to be covered by planned loan disbursements. Capricor did not issue stock, warrants or other equity to CIRM in connection with this award.

The timing of the distribution of funds pursuant to the CIRM Loan Agreement shall be contingent upon the availability of funds in the California Stem Cell Research and Cures Fund in the California State Treasury, as determined by CIRM in its sole discretion. Disbursements from time to time may be delayed or suspended in order to coincide with projected expenditures and patient enrollment.

The due diligence costs are recorded as a discount on the loan and amortized to general and administrative expenses over the remaining term of the loan. As of March 31, 2015, \$30,000 of loan costs were capitalized with the balance of \$15,506 to be amortized over approximately 2.9 years.

In February 2013, Capricor received loan proceeds of \$857,267, net of loan costs. This disbursement carries interest at the initial rate of approximately 2.8% per annum.

In July 2013, Capricor received its second disbursement under the loan award of \$3,067,799. This disbursement carries interest at the initial rate of approximately 2.5% per annum.

In April 2014, Capricor received the third disbursement under the loan award of \$4,679,947. This disbursement carries interest at the initial rate of approximately 2.6% per annum.

In July 2014, Capricor received the fourth disbursement under the loan award of \$514,177, which includes previously deducted due diligence costs that were refunded. This disbursement carries interest at the initial rate of approximately 2.6% per annum. A portion of the principal received under the third and fourth disbursements are currently being recorded as restricted cash, due to the fact that Capricor must expend approved project costs in order to use these funds. For the three months ended March 31, 2015 and 2014, interest expense under the CIRM loan was \$61,681 and \$25,327, respectively.



**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**3. STOCKHOLDERS' EQUITY**

Reverse Stock Split

On November 20, 2013, the Company effected a reverse split of its common stock, par value \$0.001 per share, at a ratio of 1-for-50. Unless otherwise indicated, all share amounts, per share data, share prices, exercise prices and conversion rates set forth in these condensed consolidated financial statements and related condensed consolidated notes, where applicable, have been adjusted retroactively to reflect this reverse stock split.

Private Placements

On January 9, 2015, the Company entered into a Share Purchase Agreement with select investors pursuant to which the Company agreed to issue and sell to the investors, in a private placement ("PIPE 1"), an aggregate of 2,839,045 shares of its common stock at a price per share of \$3.523 for an aggregate purchase price of approximately \$10,000,000.

On February 3, 2015, the Company entered into a Share Purchase Agreement with certain accredited investors, pursuant to which the Company agreed to issue and sell to the investors, in a private placement ("PIPE 2"), an aggregate of 1,658,822 shares of its common stock, par value \$0.001 per share, at a price per share of \$4.25 for an aggregate purchase price of approximately \$7,050,000.

Fees paid in conjunction with PIPE 1 and PIPE 2 amounted to \$605,736 in the aggregate and were recorded as a reduction to additional paid-in capital.

Outstanding Shares

At March 31, 2015, the Company had 16,221,985 shares of common stock issued and outstanding.

#### 4. STOCK AWARDS, WARRANTS AND OPTIONS

##### Warrants

The following table summarizes all warrant activity for the period ended March 31, 2015:

	Warrants	Weighted Average Exercise Price
Outstanding at January 1, 2015	303,881	\$ 10.02
Granted	-	-
Exercised	(15,401 )	2.27
Expired	-	-
Outstanding at March 31, 2015	288,480	\$ 10.43

**CAPRICOR THERAPEUTICS, INC.****Notes to CONDENSED CONSOLIDATED financial statements****(unaudited)****4. STOCK AWARDS, WARRANTS AND OPTIONS (continued)**

The following table summarizes all outstanding warrants to purchase shares of the Company's common stock as of March 31, 2015:

<b>At March 31, 2015</b>			
<b>Grant Date</b>	<b>Warrants Outstanding</b>	<b>Range of Exercise Prices</b>	<b>Expiration Date</b>
4/21/2010	52,650	\$ 47.00	4/21/2015
4/4/2012	187	\$ 2.27	4/4/2017
11/20/2013	235,643	\$ 2.27	11/20/2018
	<b>288,480</b>		

Restricted Stock

In August 2014, the Company granted 10,000 shares of restricted stock to one of its consultants in consideration of services to be rendered. This restricted stock grant vested monthly over a period of one year. In February 2015, the Company terminated the agreement with the consultant effective March 2015, therefore, no additional shares will be issued pursuant to the restricted stock grant. For the three months ended March 31, 2015, the Company issued 1,666 shares of that restricted common stock grant, which were valued at approximately \$8,588. The fair value of the restricted stock was determined using the Company's closing stock price on the vesting date.

Stock Options

The Company's Board of Directors (the "Board") has approved four stock option plans: (i) the Amended and Restated 2005 Stock Option Plan, (the "2005 Plan"), (ii) the 2006 Stock Option Plan, (iii) the 2012 Restated Equity Incentive Plan (which has superseded the 2006 Stock Option Plan) (the "2012 Plan"), and (iv) the 2012 Non-Employee Director Stock Option Plan (the "2012 Non-Employee Director Plan").

On August 10, 2005, the Company adopted the 2005 Plan. On July 26, 2010, the Company's stockholders approved an amendment to the 2005 Plan increasing the total number of shares authorized for issuance thereunder to 190,000. Under the 2005 Plan, incentives may be granted to officers, employees, directors, consultants and advisors. Incentives under the 2005 Plan may be granted in any one or a combination of the following forms: (i) incentive stock options and non-statutory stock options, (ii) stock appreciation rights, (iii) stock awards, (iv) restricted stock, and (v) performance shares.

At the time of the merger between Capricor and Nile became effective, 4,149,710 shares of common stock were reserved under the 2012 Plan for the issuance of stock options, stock appreciation rights, restricted stock awards and performance unit/share awards to employees, consultants and other service providers. Included in the 2012 Plan are the shares of common stock that were originally reserved under the 2006 Stock Option Plan. Under the 2012 Plan, each stock option granted will be designated in the award agreement as either an incentive stock option or a nonstatutory stock option. Notwithstanding such designation, however, to the extent that the aggregate fair market value of the shares with respect to which incentive stock options are exercisable for the first time by the participant during any calendar year (under all plans of the Company and any parent or subsidiary) exceeds \$100,000, such options will be treated as nonstatutory stock options.

At the time of the merger between Capricor and Nile became effective, 2,697,311 shares of common stock were reserved under the 2012 Non-Employee Director Plan for the issuance of stock options to members of the Board whom are not employees of the Company.

Each of the Company's stock option plans are administered by the Board, or a committee appointed by the Board, which determines the recipients and types of awards to be granted, as well as the number of shares subject to the awards, the exercise price and the vesting schedule. Currently, stock options are granted with an exercise price equal to the closing price of the Company's common stock on the date of grant, and generally vest over a period of one to four years. The term of stock options granted under each of the plans cannot exceed ten years.

The estimated weighted average fair values of the options granted during the three months ended March 31, 2015 and 2014 were approximately \$4.23 and \$10.65 per share, respectively.

**CAPRICOR THERAPEUTICS, INC.****Notes to CONDENSED CONSOLIDATED financial statements****(unaudited)****4. STOCK AWARDS, WARRANTS AND OPTIONS (continued)**

The Company estimates the fair value of each option award using the Black-Scholes option-pricing model. The Company used the following assumptions to estimate the fair value of stock options issued during the three months ended March 31, 2015 and 2014:

	March 31, 2015	March 31, 2014
Expected volatility	82%	117%
Expected term	5-7 years	7 years
Dividend yield	0%	0%
Risk-free interest rates	0.3% - 1.9%	2.2%

Employee stock-based compensation expense for the three months ended March 31, 2015 and 2014 was as follows:

	Three months ended March 31,	
	2015	2014
General and administrative	\$519,936	\$79,260
Research and development	43,597	5,284
Total	\$563,533	\$84,544

As of March 31, 2015, the total unrecognized fair value compensation cost related to non-vested stock options was approximately \$4.5 million, which is expected to be recognized over approximately 3.9 years.

Common stock, stock options or other equity instruments issued to non-employees (including consultants) as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). The fair value of stock options is determined using the Black-Scholes option-pricing model and is periodically re-measured as the underlying options vest. The fair value of any options issued to non-employees is recorded as an expense over the

applicable vesting periods.

The following table summarizes stock option activity for the three months ended March 31, 2015:

	Number of Options	Weighted Average Exercise Price
Outstanding at January 1, 2015	5,004,700	\$ 0.75
Granted	829,041	5.81
Exercised	-	-
Expired/Cancelled	(23,891 )	3.72
Outstanding at March 31, 2015	5,809,850	\$ 1.46
Exercisable at March 31, 2015	3,962,967	\$ 0.61

## 5. CONCENTRATIONS

### Cash Concentration

The Company has historically maintained checking accounts at two financial institutions. These accounts are each insured by the Federal Deposit Insurance Corporation for up to \$250,000. Historically, the Company has not experienced any significant losses in such accounts and believes it is not exposed to any significant credit risk on cash and cash equivalents. As of March 31, 2015, the Company maintained approximately \$26.0 million of uninsured deposits.

## 6. COMMITMENTS AND CONTINGENCIES

### Leases

Capricor leases space for its corporate offices pursuant to a lease that is effective for a two year period beginning July 1, 2013 with an option to extend the lease for an additional twelve months. The monthly lease payment was \$16,620 per month for the first twelve months of the term and increased to \$17,285 per month for the second twelve months of the term. On March 3, 2015, Capricor executed a Second Amendment to Lease with The Bubble Real Estate Company, LLC, pursuant to which (i) additional space was added to the Company's corporate office lease and (ii) the Company exercised its option to extend the lease term through June 30, 2016. Under the terms of the amendment, commencing February 2, 2015, the base rent was \$17,957 for one month, and, commencing March 2, 2015, the base rent increased to \$21,420 per month for four months. Commencing July 1, 2015, the base rent will increase to \$22,111 per month for the remainder of the lease term.



**CAPRICOR THERAPEUTICS, INC.****Notes to CONDENSED CONSOLIDATED financial statements****(unaudited)****6. COMMITMENTS AND CONTINGENCIES (continued)**

On May 14, 2014, Capricor entered into a facilities lease with Cedars-Sinai Medical Center (“CSMC”), a shareholder of the Company, for two research labs (the “Facilities Lease”). The Facilities Lease is for a term of three years commencing June 1, 2014 and replaces the month-to-month lease that was previously in effect between CSMC and Capricor. The monthly lease payment was approximately \$15,461 per month for the first six months of the term and increased to approximately \$19,350 per month for the remainder of the term. The amount of rent expense is subject to annual adjustments according to increases in the Consumer Price Index.

Unless renewed, each of the leases described above will not be in effect in the year 2018. A summary of future minimum rental payments required under operating leases as of March 31, 2015 are as follows:

Years ended	Operating Leases
2015	\$ 371,076
2016	364,866
2017	96,750
Total minimum lease payments	<b>\$832,692</b>

Expense incurred under operating leases to unrelated parties was approximately \$60,677 and \$49,860 for the three months ended March 31, 2015 and 2014, respectively. Expense incurred under operating leases to related parties was approximately \$56,105 and \$13,662 for the three months ended March 31, 2015 and 2014, respectively.

Legal Contingencies

Periodically, the Company may become involved in certain legal actions and claims arising in the ordinary course of business. There were no material legal actions or claims reported at March 31, 2015.



## 7. LICENSE AGREEMENTS

### Capricor's Technology - CAP-1002, CAP-1001, CSps and Exosomes

Capricor has entered into exclusive license agreements for intellectual property rights related to cardiac derived cells with Università Degli Studi Di Roma at la Sapienza (the "University of Rome"), The Johns Hopkins University ("JHU") and CSMC. In addition, Capricor has filed patent applications related to enhancements or validation of the technology developed by its own scientists.

### University of Rome License Agreement

Capricor and the University of Rome entered into a License Agreement, dated June 21, 2006 (the "Rome License Agreement"), which provides for the grant of an exclusive, world-wide, royalty-bearing license by the University of Rome to Capricor (with the right to sublicense) to develop and commercialize licensed products under the licensed patent rights in all fields. With respect to any new or future patent applications assigned to the University of Rome utilizing cardiac stem cells in cardiac care, Capricor has a first right of negotiation for a certain period of time to obtain a license thereto.

Pursuant to the Rome License Agreement, Capricor paid the University of Rome a license issue fee, is currently paying minimum annual royalties in the amount of 20,000 Euros per year, and is obligated to pay a lower-end of a mid-range double-digit percentage on all royalties received as a result of sublicenses granted, which are net of any royalties paid to third parties under a license agreement from such third party to Capricor. The minimum annual royalties are creditable against future royalty payments. Capricor had accrued royalties of approximately \$19,581 and \$14,181 recorded as accounts payable and accrued expenses as of March 31, 2015 and December 31, 2014, respectively.

The Rome License Agreement will, unless extended or sooner terminated, remain in effect until the later of the last claim of any patent or until any patent application comprising licensed patent rights has expired or been abandoned. Under the terms of the Rome License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy. Either party will have up to 90 days to cure its material breach.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**7. LICENSE AGREEMENTS (continued)**

The Johns Hopkins University License Agreement

Capricor and JHU entered into an Exclusive License Agreement, effective June 22, 2006 (the “JHU License Agreement”), which provides for the grant of an exclusive, world-wide, royalty-bearing license by JHU to Capricor (with the right to sublicense) to develop and commercialize licensed products and licensed services under the licensed patent rights in all fields and a nonexclusive right to the know-how. In May 2009, the JHU License Agreement was amended to add additional patent rights to the JHU License Agreement in consideration of a payment to JHU and reimbursement of patent costs. Capricor and JHU executed a Second Amendment to the JHU License Agreement, effective as of December 20, 2013, pursuant to which, among other things, certain definitions were added or amended, the timing of certain obligations was revised and other obligations of the parties were clarified.

Pursuant to the JHU License Agreement, JHU was paid an initial license fee and, thereafter, Capricor is required to pay minimum annual royalties on the anniversary dates of the JHU License Agreement. The minimum annual royalties range from \$5,000 on the first and second anniversary dates to \$20,000 on the tenth anniversary date and thereafter. The minimum annual royalties are creditable against a low single-digit running royalty on net sales of products and net service revenues, which Capricor is also required to pay under the JHU License Agreement, which running royalty may be subject to further reduction in the event that Capricor is required to pay royalties on any patent rights to third parties in order to make or sell a licensed product. In addition, Capricor is required to pay a low double-digit percentage of the consideration received by it from sublicenses granted, and is required to pay JHU certain defined development milestone payments upon the successful completion of certain phases of its clinical studies and upon receiving approval from the U.S. Food and Drug Administration (the “FDA”). The development milestones range from \$100,000 upon successful completion of a full Phase I clinical study to \$1,000,000 upon full FDA market approval and are fully creditable against payments owed by Capricor to JHU on account of sublicense consideration attributable to milestone payments received from a sublicensee. The maximum aggregate amount of milestone payments payable under the JHU License Agreement, as amended, is \$1,850,000. As of March 31, 2015 and December 31, 2014, \$100,000 was recorded within accounts payable and accrued expenses as a development milestone due to the fact that Phase I of the ALLSTAR study enrollment had been completed. Also, the Company had an accrued royalty of approximately \$7,500 and \$5,000 recorded as accounts payable and accrued expenses as of March 31, 2015 and December 31, 2014, respectively.

The JHU License Agreement will, unless sooner terminated, continue in effect in each applicable country until the date of expiration of the last to expire patent within the patent rights, or, if no patents are issued, then for twenty years from the effective date. Under the terms of the JHU License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy, or fail to cure a material breach within 30 days after notice. In addition, Capricor may terminate for any reason upon 60 days' written notice.

#### Cedars-Sinai Medical Center License Agreement

On January 4, 2010, Capricor entered into an Exclusive License Agreement with CSMC (the "CSMC License Agreement"), for certain intellectual property rights. In 2013, the CSMC License Agreement was amended twice resulting in, among other things, a reduction in the percentage of sublicense fees which would have been payable to CSMC. Effective December 30, 2013, Capricor entered into an Amended and Restated Exclusive License Agreement with CSMC (the "Amended CSMC License Agreement"), pursuant to which, among other things, certain definitions were added or amended, the timing of certain obligations was revised and other obligations of the parties were clarified.

The Amended CSMC License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) to conduct research using the patent rights and know-how and develop and commercialize products in the field using the patent rights and know-how. In addition, Capricor has the exclusive right to negotiate for an exclusive license to any future rights arising from related work conducted by or under the direction of Dr. Eduardo Marbán on behalf of CSMC. In the event the parties fail to agree upon the terms of an exclusive license, Capricor will have a non-exclusive license to such future rights, subject to royalty obligations.

Pursuant to the CSMC License Agreement, CSMC was paid a license fee and Capricor was obligated to reimburse CSMC for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor is required to meet certain spending and development milestones. The annual spending requirements range from \$350,000 to \$800,000 each year between 2010 and 2017 (with the exception of 2014, for which there was no annual spending requirement). Pursuant to the Amended CSMC License Agreement, Capricor remains obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a low double-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third party for patent rights in connection with the royalty-bearing product. In 2010, Capricor discontinued its research under some of the patents.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**7. LICENSE AGREEMENTS (continued)**

The Amended CSMC License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Amended CSMC License Agreement, unless waived by CSMC, the agreement shall automatically terminate: (i) if Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) within 90 days if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. Capricor may terminate the agreement if CSMC fails to cure any material breach within 90 days after notice.

On March 20, 2015, Capricor and CSMC entered into a First Amendment to the Amended CSMC License Agreement, pursuant to which the parties agreed to delete certain patent applications from the list of Scheduled Patents which Capricor determined not to be material to the portfolio.

Exosomes License Agreement

On May 5, 2014, Capricor entered into an Exclusive License Agreement with CSMC (the “Exosomes License Agreement”), for certain intellectual property rights related to exosomes technology. The Exosomes License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) in order to conduct research using the patent rights and know-how and to develop and commercialize products in the field using the patent rights and know-how. In addition, Capricor has the exclusive right to negotiate for an exclusive license to any future rights arising from related work conducted by or under the direction of Dr. Eduardo Marbán on behalf of CSMC. In the event the parties fail to agree upon the terms of an exclusive license, Capricor shall have a non-exclusive license to such future rights, subject to royalty obligations.

Pursuant to the Exosomes License Agreement, CSMC was paid a license fee and Capricor reimbursed CSMC for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor is required to meet certain non-monetary development milestones and is obligated to pay low single-digit royalties on

sales of royalty-bearing products as well as a single-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third party for patent rights in connection with the royalty bearing product.

The Exosomes License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Exosomes License Agreement, unless waived by CSMC, the agreement shall automatically terminate: (i) if Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) within 90 days if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. Capricor may terminate the agreement if CSMC fails to cure any material breach within 90 days after notice.

On February 27, 2015, Capricor and CSMC entered into a First Amendment to Exclusive License Agreement, thereby amending the Exosomes License Agreement (the “Exosomes License Amendment”). Under the Exosomes License Amendment, (i) the description of patent rights in Schedule A has been replaced by a Revised Schedule A that includes four additional patent applications; (ii) Capricor was required to pay CSMC an upfront fee of \$20,000; (iii) Capricor is required to reimburse CSMC approximately \$34,000 for attorneys’ fees and filing fees that were incurred in connection with the additional patent rights; and (iv) Capricor is required to pay CSMC certain defined product development milestone payments upon reaching certain phases of its clinical studies and upon receiving approval of a product from the FDA. The product development milestones range from \$15,000 upon the dosing of the first patient in a Phase I clinical trial of a product to \$75,000 upon receipt of FDA approval of a product. The maximum aggregate amount of milestone payments payable under the Exosomes License Agreement, as amended, is \$190,000.

As noted above, Capricor is party to lease agreements with CSMC, which holds more than 10% of the outstanding capital stock of Capricor Therapeutics (see Note 6 – “Commitments and Contingencies”). Additionally, Dr. Eduardo Marbán, who holds more than 10% of the outstanding capital stock of Capricor Therapeutics, is the Director of the Cedars-Sinai Heart Institute and the Co-Founder of Capricor and Scientific Advisory Board Chairman of Capricor.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**7. LICENSE AGREEMENTS (continued)**

Collaboration Agreement with Janssen Biotech, Inc.

On December 27, 2013, Capricor entered into a Collaboration Agreement and Exclusive License Option (the “Janssen Agreement”) with Janssen, a wholly-owned subsidiary of Johnson & Johnson. Under the terms of the Janssen Agreement, Capricor and Janssen agreed to collaborate on the development of Capricor’s cell therapy program for cardiovascular applications, including its lead product candidate, CAP-1002. Capricor and Janssen further agreed to collaborate on the development of cell manufacturing in preparation for future clinical trials. Under the Janssen Agreement, Capricor was paid \$12.5 million, and Capricor will contribute to the development of a chemistry, manufacturing and controls (“CMC”) package. In addition, Janssen has the exclusive right to enter into an exclusive license agreement pursuant to which Janssen would receive a worldwide, exclusive license to exploit CAP-1002 as well as certain allogeneic cardiospheres and cardiosphere-derived cells in the field of cardiology. Janssen has the right to exercise the option at any time until 60 days after the delivery by Capricor of the six-month follow-up results from Phase II of Capricor’s ALLSTAR clinical trial for CAP-1002. If Janssen exercises its option rights, Capricor would receive an upfront license fee and additional milestone payments, which may total up to \$325.0 million. In addition, a royalty ranging from a low double-digit percentage to a lower-end of a mid-range double-digit percentage would be paid on sales of licensed products.

Company Technology – Cenderitide and CU-NP

The Company has entered into an exclusive license agreement for intellectual property rights related to natriuretic peptides with the Mayo Foundation for Medical Education and Research (“Mayo”), a Clinical Trial Funding Agreement with Medtronic, Inc. (“Medtronic”), and a Transfer Agreement with Medtronic, all of which also include certain intellectual property licensing provisions.

Mayo License Agreement

The Company and Mayo previously entered into a Technology License Agreement with respect to Cenderitide on January 20, 2006, which was filed as Exhibit 10.6 to the Company's Current Report on Form 8-K filed with the SEC on September 21, 2007, and which was amended on June 2, 2008 (as so amended, the "CD-NP Agreement"). On June 13, 2008, the Company and Mayo entered into a Technology License Agreement with respect to CU-NP (the "CU-NP Agreement"), which was filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2008. On November 14, 2013, the Company entered into an Amended and Restated License Agreement with Mayo (the "Amended Mayo Agreement"). The Amended Mayo Agreement amends and restates in its entirety each of the CD-NP Agreement and the CU-NP Agreement, and creates a single amended and restated license agreement between the Company and Mayo with respect to CD-NP and CU-NP.

The Amended Mayo Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by Mayo to the Company (with the right to sublicense) under the Mayo patents, patent applications and improvements, and a nonexclusive right under the know-how, for the development and commercialization of CD-NP and CU-NP in all therapeutic indications. With respect to any future patents and any improvements related to Cenderitide and CU-NP owned by or assigned to Mayo, the Company has the exclusive right of first negotiation for the exclusive or non-exclusive rights (at the Company's option) thereto. Such exclusive right of negotiation shall be effective as of June 1, 2016, or such earlier date when the Company has satisfied certain payment obligations to Mayo.

Under each of the previous CD-NP Agreement and CU-NP Agreement, the Company paid Mayo up-front cash payments and the Company agreed to make certain performance-based cash payments to Mayo upon successful completion of certain milestones. Additionally, the Company issued certain amounts of common stock of the Company to Mayo under each agreement. The Amended Mayo Agreement restructured the economic arrangements of the CD-NP Agreement and the CU-NP Agreement by, among other things, eliminating certain milestone payments and decreasing the royalty percentages payable upon the commercial sale of the products to low single-digit royalties on sales of CD-NP and CU-NP products. The Company is also obligated to pay to Mayo a low single-digit percentage on any upfront consideration or milestone payment received in connection with a sublicense. The Company is further obligated to pay to Mayo a low single-digit percentage on any consideration received in connection with an assignment of rights under the Amended Mayo Agreement. Pursuant to the terms of the Amended Mayo Agreement, the Company agreed to pay to Mayo an annual license maintenance fee and to issue to Mayo an additional 18,000 shares of the Company's common stock as additional consideration for the grant of certain rights. Mayo also agreed to waive or defer the payment of certain fees owed to Mayo. All breaches and defaults by the Company under the terms of the CD-NP Agreement and CU-NP Agreement were waived by Mayo in the Amended Mayo Agreement.

The Amended Mayo Agreement will, unless sooner terminated, expire on the later of (a) the expiration of the last to expire valid claim contained in the Mayo patents, or (b) the 20th anniversary of the Amended Mayo Agreement. Under the terms of the Amended Mayo Agreement, Mayo may terminate the agreement earlier (i) for the Company's material breach of the agreement that remains uncured for 90 days' after written notice to the Company, (ii) for the Company's insolvency or bankruptcy, (iii) if the Company challenges the validity or enforceability of any of the patent rights in any manner, or (iv) if the Company has not initiated either the next clinical trial of Cenderitide within two years of the effective date of the Amended Mayo Agreement or a clinical trial of CU-NP within two and one-half years of the effective date. Such condition was satisfied when the Company initiated its clinical trial of Cenderitide in January 2015. The Company may terminate the Amended Mayo Agreement without cause upon 90 days' written notice.





**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**7. LICENSE AGREEMENTS (continued)**

Medtronic Clinical Trial Funding Agreement

In February 2011, the Company entered into a Clinical Trial Funding Agreement with Medtronic. Pursuant to the agreement, Medtronic provided funding and equipment necessary for the Company to conduct a Phase I clinical trial to assess the pharmacokinetics and pharmacodynamics of Cenderitide when delivered to heart failure patients through continuous subcutaneous infusion using Medtronic's pump technology.

The agreement provided that intellectual property conceived in or otherwise resulting from the performance of the Phase I clinical trial will be jointly owned by the Company and Medtronic (the "Joint Intellectual Property"), and that the Company is to pay royalties to Medtronic based on the net sales of a product covered by the Joint Intellectual Property. The agreement further provided that, if the parties fail to enter into a definitive commercial license agreement with respect to Cenderitide, each party will have a right of first negotiation to license exclusive rights to any Joint Intellectual Property.

Pursuant to its terms, the agreement expired in February 2012, following the completion of the Phase I clinical trial and the delivery of data and reports related to such study. Although the Medtronic agreement expired, there are certain provisions that survive the expiration of the agreement, including the obligation to pay royalties on products that might be covered by the Joint Intellectual Property. The Company and Medtronic have subsequently entered into a Transfer Agreement, described below.

Medtronic Transfer Agreement

On October 8, 2014, the Company entered into a Transfer Agreement (the "Transfer Agreement") with Medtronic to acquire patent rights relating to the formulation and pump delivery of natriuretic peptides. Pursuant to the Transfer Agreement, Medtronic has assigned to the Company all of its right, title and interest in all natriuretic peptide patents and patent applications previously owned by Medtronic or co-owned by Medtronic and the Company ("Natriuretic Peptide Patents"). Under the Transfer Agreement, the Company received all rights to the Natriuretic Peptide Patents,

including the right to grant licenses and to make assignments without approval from Medtronic.

The Transfer Agreement became effective on October 8, 2014 and will expire simultaneously at the expiration of the last to expire of the valid claims. Both parties have the right to terminate the Transfer Agreement upon 30 days written notice to the other party in the event of a default which has not been cured within such 30-day period. In addition, Medtronic had the right to terminate the Transfer Agreement and to have the rights to the Natriuretic Peptide Patents reassigned to it by the Company if either the Company, an affiliate, or a non-party licensee failed to commence a clinical trial of a CD-NP product within 18 months from the effective date. Such condition was satisfied when the Company initiated its clinical trial of Cenderitide in January 2015.

In the event of a termination of the Transfer Agreement, (i) the Natriuretic Peptide Patents which were not owned or co-owned by the Company prior to the effective date of the Transfer Agreement shall be assigned back to Medtronic; (ii) the Company's rights in the Natriuretic Peptide Patents that were co-owned by Capricor pursuant to the Clinical Trial Funding Agreement will remain with the Company, subject to the surviving terms and provisions thereof; and (iii) the Company shall assign back to Medtronic those rights that were co-owned by Medtronic pursuant to the Clinical Trial Funding Agreement.

Pursuant to the Transfer Agreement, Medtronic was paid an upfront payment of \$100,000, and the Company is obligated to pay Medtronic a mid-single-digit royalty on net sales of products, a low double-digit percentage of any consideration received from any sublicenses or other grant of rights, and a mid-double-digit percentage of any monetary awards or settlements received by the Company as a result of enforcement of the Natriuretic Peptide Patents against a non-party entity, less the costs and attorney's fees incurred to enforce the Natriuretic Peptide Patents. In addition, there are additional payments that may become due from the Company upon the achievement of certain defined milestones, which payments, in the aggregate, total up to \$7.0 million.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**8. RELATED PARTY TRANSACTIONS**

Lease and Sub-Lease Agreements

As noted above, Capricor Therapeutics is party to lease agreements with CSMC, which holds more than 10% of the outstanding capital stock of Capricor Therapeutics (see Note 6 – “Commitments and Contingencies”). Additionally, Dr. Eduardo Marbán, who holds more than 10% of the outstanding capital stock of Capricor Therapeutics, is the Director of the Cedars-Sinai Heart Institute, the Co-Founder of Capricor and Scientific Advisory Board Chairman of Capricor.

Beginning May 1, 2012, pursuant to a sublease agreement, Capricor subleased part of its office space to Frank Litvack, the Company’s Executive Chairman and a member of its Board of Directors, for \$2,500 per month. On April 1, 2013, Capricor entered into a sublease with Reprise Technologies, LLC, a limited liability company which is wholly owned by Dr. Litvack, for \$2,500 per month. The sublease is on a month-to-month basis. For each of the three-month periods ended March 31, 2015 and 2014, Capricor recognized \$7,500 in sublease income from the related party. Sublease income is recorded as a reduction to general and administrative expenses.

Consulting Agreements

Effective May 1, 2012, Frank Litvack, the Company’s Executive Chairman, entered into a consulting agreement with Capricor whereby Capricor was obligated to pay Dr. Litvack fees of \$4,000 per month for consulting services. Effective January 1, 2013, the payment amount was increased to \$10,000 per month payable for consulting services. The agreement is terminable upon 30 days’ notice. On March 24, 2014, Capricor entered into a consulting agreement with Dr. Litvack memorializing the \$10,000 per month compensation arrangement described above.

Payables to Related Party

At March 31, 2015 and December 31, 2014, the Company had accounts payable and accrued expenses to related parties totaling \$632,699 and \$433,712, respectively. CSMC accounts for approximately \$620,057 and \$421,328 of the total accounts payable and accrued expenses to related parties as of March 31, 2015 and December 31, 2014, respectively.

## **9.SUBSEQUENT EVENTS**

### 2010 Warrants Expiration

On April 21, 2015, warrants to purchase 52,650 shares of common stock with an exercise price of \$47.00 expired pursuant to the terms of the applicable warrant agreement.

## **Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.**

*The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the condensed consolidated notes to those statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, our actual results may differ materially from those anticipated in these forward-looking statements.*

*As used in this Quarterly Report on Form 10-Q, references to “Capricor Therapeutics,” the “Company,” “we,” “us,” “our” or similar terms include Capricor Therapeutics, Inc. and its wholly-owned subsidiary. References to “Capricor” are with respect to Capricor, Inc., which became our wholly-owned subsidiary upon completion of the merger between Capricor and Nile Therapeutics, Inc. on November 20, 2013.*

### **Overview**

Our mission is to improve the treatment of diseases by commercializing innovative therapies, with a primary focus on cardiovascular diseases. Our executive offices are located at 8840 Wilshire Blvd., 2<sup>nd</sup> Floor, Beverly Hills, California 90211. Our telephone number is (310) 358-3200 and our Internet address is [www.capricor.com](http://www.capricor.com).

### ***Consummation of the Merger***

On November 20, 2013, pursuant to that certain Agreement and Plan of Merger and Reorganization dated as of July 7, 2013, as amended by that certain First Amendment to Agreement and Plan of Merger and Reorganization dated as of September 27, 2013, or, as so amended, the Merger Agreement, by and among Nile Therapeutics, Inc., a Delaware corporation, or Nile, Bovet Merger Corp., a Delaware corporation and a wholly-owned subsidiary of Nile, or Merger Sub, and Capricor, Inc., or Capricor, Merger Sub merged with and into Capricor and Capricor became a wholly-owned subsidiary of Nile. Immediately prior to the effective time of the merger, or the Effective Time, and in connection therewith, Nile filed certain amendments to its certificate of incorporation which, among other things (i) effected a 1-for-50 reverse split of its common stock, (ii) changed its corporate name from “Nile Therapeutics, Inc.” to “Capricor Therapeutics, Inc.,” and (iii) effected a reduction in the total number of authorized shares of common stock from 100,000,000 to 50,000,000, and a reduction in the total number of authorized shares of preferred stock from 10,000,000 to 5,000,000.

Capricor, our wholly-owned subsidiary, was founded in 2005 as a Delaware corporation based on the innovative work of its founder, Eduardo Marbán, M.D., Ph.D., and his collaborators. First located in Baltimore, Maryland, adjacent to The Johns Hopkins University, or JHU, where Dr. Marbán was chief of cardiology, Capricor moved to Los Angeles, California in 2007 when Dr. Marbán become Director of the Heart Institute at Cedars-Sinai Medical Center, or CSMC. Capricor's laboratories are located in space that Capricor leases from CSMC.

We currently have six drug candidates in various stages of development:

**CAP-1002:** Capricor's lead product candidate consists of allogeneic cardiosphere-derived cells, or CDCs. CAP-1002 is currently being tested in Capricor's ALLSTAR Phase II clinical trial, which will determine if the cells can lead to reduction in scar size in patients who have had a heart attack. It is a dual cohort clinical trial that has two independently recruiting strata: the first are patients who have recently experienced a myocardial infarction, or MI (30-90 days post MI); the second are patients who have suffered an MI within one year (90 days to one-year post MI) to see if the cells can reduce the size of older, more established scar. In addition to measuring scar size, ALLSTAR will also look at a variety of clinical and quality of life endpoints. Phase I of the ALLSTAR trial was a 14 patient trial conducted at three sites to determine if allogeneic CDCs are safe for patients. Phase I of the trial was funded in large part by a grant received from the National Institutes of Health, or NIH. The primary endpoints focused on acute effects of cell delivery and potential immune consequences of allogeneic cell delivery. Patient enrollment was completed for the Phase I portion of the trial on October 11, 2013. Preliminary 12 month MRI data collected on the patients in the Phase I open-label dose-escalation study revealed that those patients who would be included in the Phase II clinical study by virtue of dose and tissue type compatibility exhibited measurable improvement in ejection fraction, a global measure of the heart's pumping ability. Ejection fraction improved by 5.2%. Additionally, there was a relative reduction in scar size of 20.7%. Measurements of viable mass and regional function also showed quantifiable improvement.

On December 15, 2013, Capricor received notification from the National Heart Lung and Blood Institute, or the NHLBI, Gene and Cell Therapy Data Safety Monitoring Board that the 14-patient Phase I portion had met its safety endpoints and that Capricor was cleared to begin the Phase II portion of the trial. Capricor began enrollment of the Phase II portion of the ALLSTAR study in the first quarter of 2014. Phase II is an estimated 300 patient, double-blind, randomized, placebo-controlled trial which is powered to detect a reduction in infarct (scar) size as measured by MRI in both groups of patients, those with recent and chronic MI, at the one year follow-up. To date, enrollment in the Phase II portion of the study has been slower than expected, however Capricor is actively pursuing additional initiatives to increase the rate of enrollment which may include adding additional sites in the US and Canada. It is Capricor's intent to perform an interim analysis which, if successful, could result in a reduction in the number of patients necessary for achieving statistical significance and meeting the primary endpoint which is reduction in infarct size at 12 months post infusion. This plan is subject to the concurrence of interested parties, including the FDA. As infarct size was reduced significantly in the CADUCEUS treated patients at six months (as discussed below), Capricor intends to get a preliminary readout of ALLSTAR Phase II at six months post infusion. Phase II of the ALLSTAR study is being funded in large part through the support of the California Institute for Regenerative Medicine, or CIRM.

In December 2013, Capricor entered into a Collaboration Agreement and Exclusive License Option with Janssen Biotech, Inc., or Janssen. Under the agreement, Janssen has an exclusive option to enter into an exclusive license agreement with Capricor, pursuant to which, if exercised, Janssen would receive a worldwide, exclusive license to exploit CAP-1002 as well as certain allogeneic cardiospheres and cardiosphere-derived cells in the field of cardiology, except as may otherwise be agreed with respect to certain indications.

Additionally, Capricor has been awarded a grant for approximately \$3.0 million from the NIH to support further development of the CAP-1002 product. In June 2014, we received approval from the NIH to use the funds from the grant for the first part of the DYNAMIC (dilated cardiomyopathy intervention with allogeneic myocardially-regenerative cells) trial, which is being sponsored by Capricor. The first part of the DYNAMIC trial used CAP-1002 to treat patients with advanced heart failure utilizing triple-vessel intracoronary infusion. We initiated enrollment of the DYNAMIC trial in December 2014 and completed enrollment in April 2015. Initial top-line results are expected to be reported in late 2015.

Furthermore, in October 2014, we announced plans to pursue a clinical program utilizing CAP-1002 as a potential treatment for Duchenne Muscular Dystrophy, or DMD. The planned clinical program will aim to treat cardiac dysfunction associated with the disease. We have submitted an investigational new drug, or IND, application, based, in part, on pre-clinical data findings from the laboratory of Dr. Eduardo Marbán. If an IND is received in 2015, we are planning to initiate a clinical trial in 2015. Additionally, in April 2015, Capricor was granted orphan drug designation by the FDA for CAP-1002 for the treatment of cardiomyopathy associated with DMD.

**Cenderitide (CD-NP):** Cenderitide belongs to a class of drugs called natriuretic peptides. Preclinical and clinical data have shown that the natriuretic peptide class can act on multiple disease processes that play a role in negative outcomes associated with heart failure. Cenderitide's treatment goal and target indication is to provide a novel and effective therapeutic option for the outpatient treatment of heart failure, thereby addressing a critical unmet need. Cenderitide is being designed as an outpatient therapy to be delivered continuously using a validated subcutaneous infusion pump for up to 90 days (the "post-acute" period) following an acute heart failure hospital admission, as well as for other potential indications. Cenderitide was designed by scientists at the Mayo Clinic to be the only dual natriuretic peptide receptor agonist. We initiated a Phase II clinical study of Cenderitide in January 2015 and completed enrollment in March 2015. Additionally, we entered into an Investigator-Initiated Research Support Agreement with Insulet Corporation. Pursuant to the agreement with Insulet, Insulet agreed to support our research by engaging in certain product development, project management and design control activities in addition to product supply for the Cenderitide clinical trial. We are utilizing the Insulet drug delivery system based on the OmniPod® technology. The trial enrolled 14 patients with stable, chronic heart failure. Patients received up to eight consecutive days of Cenderitide through subcutaneous infusion using Insulet's drug delivery system technology. This study will assess the safety and tolerability, pharmacokinetics profiles and pharmacodynamic response to increasing dose levels of open-label Cenderitide administered in a stepwise fashion. If the safety criteria are met in this Phase II study, Capricor will determine whether to conduct additional clinical studies to further assess the safety and efficacy of this product candidate. Initial topline results are expected to be reported in mid to late 2015.

**Exosomes:** Exosomes are nano-sized, membrane-enclosed vesicles, or “bubbles”, that are filled with select molecules, including proteins and microRNAs, which, when released, send messages to neighboring cells to regulate cellular functions. Exosomes act as a transport vehicle out of the cell for microRNA, other fragments of genetic material and proteins that act as messengers between cells, ultimately providing regulatory function for many cell processes, including inflammation, angiogenesis, programmed cell death (apoptosis) and scarring. Pre-clinical research has shown that exogenous exosomes can be used as therapeutic agents aimed to direct or, in some cases, re-direct cellular activities. Their size, ease of crossing cell membranes, and ability to communicate in native cellular language makes them a class of exciting and novel therapeutic agents. We are currently in pre-clinical testing to explore the possible future therapeutic benefits that exosomes may possess.

**CAP-1001:** CAP-1001 consists of autologous CDCs. This product was used in the Phase I CADUCEUS clinical trial, which was sponsored and conducted by CSMC in collaboration with JHU. In that study, 25 patients were enrolled, 17 of which received autologous CDCs. 16 of the 17 treated patients showed a mean reduction of approximately 45% in scar mass and an increase in viable heart muscle one-year post heart attack. The eight patients in the control group had no significant change in infarct (scar) size. At present, there is no plan for another clinical trial for CAP-1001. The data from CADUCEUS, using autologous CDCs, suggests that the cells are effective in reducing scar within several months of a heart attack. The ALLSTAR trial is designed to validate the results of CADUCEUS using an allogeneic product while also looking for potential efficacy in patients between 90 days and one year post MI with a more chronic scar, a patient population that CADUCEUS was not designed to study.



**CU-NP:** CU-NP is a pre-clinical rationally-designed natriuretic peptide that consists of amino acid chains identical to those produced by the human body, specifically the ring structure of C-type natriuretic peptide, or CNP, and the N- and C-termini of Urodilatin, or URO. We are currently evaluating whether we will proceed with clinical development of this product.

**CSps:** CSps are multicellular clusters called cardiospheres, a 3D micro-tissue from which CDCs are derived, and have shown significant healing effects in pre-clinical models of heart failure. While Capricor considers the CSps an important product, at present there is no plan for a clinical trial for CSps.

We have no product sales to date and will not have the ability to generate any product revenue until after we have received approval from the FDA or equivalent foreign regulatory bodies to begin selling our pharmaceutical product candidates. Developing pharmaceutical products is a lengthy and very expensive process. Even if we obtain the capital necessary to continue the development of our product candidates, whether through a strategic transaction or otherwise, we do not expect to complete the development of a product candidate for many years, if ever. To date, most of our development expenses have related to our product candidates, CAP-1002 and Cenderitide. As we proceed with the clinical development of CAP-1002 and other potential indications for CAP-1002, and as we further develop Cenderitide or other additional products, our expenses will further increase. To the extent that we are successful in acquiring additional product candidates for our development pipeline, our need to finance further research and development activities will continue increasing. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development of the products. Our major sources of working capital have been proceeds from private and public equity sales, grants received from the NIH, a payment from Janssen and a loan award from CIRM.

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs, supplies, clinical trial costs, patient treatment costs, consulting fees, costs of personnel and supplies for manufacturing, costs of service providers for pre-clinical, clinical and manufacturing, and certain legal expenses resulting from intellectual property prosecution, stock compensation expense and other expenses relating to the design, development, testing and enhancement of our product candidates. Except for certain capitalized intangible assets, R&D costs are expensed as incurred.

General and administrative, or G&A, expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, stock compensation expense, accounting, legal and other professional fees, consulting expenses, rent for corporate offices, business insurance and other corporate expenses.

Our results have included non-cash compensation expense due to the issuance of stock options and warrants, as applicable. We expense the fair value of stock options and warrants over their vesting period as applicable. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. The terms and vesting schedules for share-based awards vary by type of grant and the

employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial performance and product development. Stock-based compensation expense is included in the consolidated statements of operations under G&A or R&D expenses, as applicable. We expect to record additional non-cash compensation expense in the future, which may be significant.

## **Results of Operations**

*General and Administrative Expenses.* G&A expenses for the three months ended March 31, 2015 and 2014 were approximately \$1.4 million and \$0.9 million, respectively. The increase in the first quarter of 2015 of approximately \$0.5 million compared to the same period of 2014 is attributable to an increase of approximately \$0.1 million in compensation and recruiting costs related to increased headcount. Furthermore, there was an increase of approximately \$0.4 million related to stock based compensation expense in the three months ended March 31, 2015 as compared to the same period of 2014.

*Research and Development Expenses.* R&D expenses for the three months ended March 31, 2015 and 2014 were approximately \$3.8 million and \$1.4 million, respectively. The increase of approximately \$2.4 million in the first quarter of 2015 over the same period of 2014 is primarily due to the fact that Capricor was actively conducting clinical trial activities of CAP-1002 (DYNAMIC and ALLSTAR) and Cenderitide in 2015 while we continued our research and development efforts. This resulted in an increase of approximately \$2.1 million in clinical costs primarily related to contract research organizations, manufacturing costs associated with CAP-1002 and Cenderitide, as well as patient costs and expenses for the operational team that supports our clinical trials. Additionally, for the three months ended March 31, 2015 there was an increase of approximately \$0.1 million in R&D expenses related to our Janssen CMC development and process development work as compared to the same period in 2014. Furthermore, there was an increase in general R&D expenses related to our product candidates, including exosomes, of approximately \$0.2 million for the three months ended March 31, 2015 as compared to the same period of 2014.

*CAP-1002* – Although the development of CAP-1002 is in its early stages, we believe that it has the potential to treat heart disease and its complications. On December 15, 2013, the NHLBI Gene and Cell Therapy Data Safety Monitoring Board gave Capricor approval to move into the Phase II portion of the ALLSTAR trial. We expect to spend approximately \$10.0 million to \$14.0 million during 2015 on the development of CAP-1002, which is primarily related to our Phase II ALLSTAR trial and the DYNAMIC trial. The Phase I portion of the ALLSTAR trial was funded in large part through a grant received from the NIH. We began enrollment of the Phase II portion of the ALLSTAR trial in the first quarter of 2014. Phase II is an estimated 300 patient, double-blind, placebo-controlled, multi-centered study in which CAP-1002 will be administered to patients via intracoronary infusion within 30 days to one year following a heart attack. Capricor is actively pursuing additional initiatives to increase the rate of enrollment which may include adding additional sites in the US and Canada. It is Capricor's intent to perform an interim analysis which, if successful, could result in a reduction in the number of patients necessary for achieving statistical significance and meeting the primary endpoint which is reduction in infarct size at 12 months post infusion. This plan is subject to the concurrence of interested parties, including the FDA. Phase II is funded in large part through the support of a loan award from CIRM for approximately \$19.8 million. The trial will measure several endpoints, including infarct size. Additional endpoints include left ventricular end-systolic and diastolic volume and ejection fraction at six and twelve months. Our strategy for further development of CAP-1002 will depend to a large degree on the outcome of these planned studies. Capricor recently completed enrollment of the first part of the DYNAMIC clinical trial. DYNAMIC is funded in large part through a grant award from the NIH. Except as may otherwise be agreed with respect to certain indications, if Janssen exercises its exclusive option under the Collaboration Agreement and Exclusive License Option between the Company and Janssen, or the Janssen Agreement, Janssen will thereafter be responsible for any additional trials and future development costs with respect to CAP-1002. Furthermore, if we proceed with the initiation of a clinical trial, after approval from the FDA with respect to an IND for the use of CAP-1002 for the treatment of DMD, we expect our expenses to increase further.

*Cenderitide* – We acquired the rights to Cenderitide in 2006, and have incurred substantial losses surrounding the development of the product to date. Prior to the merger between Capricor and Nile, Nile had incurred approximately \$19.9 million in expenses directly relating to the Cenderitide development program through September 30, 2013. We recently announced completion of enrollment of a Phase II study with Cenderitide. We expect to spend approximately \$1.0 million to \$2.0 million during 2015 in development expenses related to the Cenderitide clinical program. Capricor will determine whether to conduct additional clinical studies to further assess the safety and efficacy of this product candidate.

*CAP-1001* – In 2011, CSMC, in collaboration with JHU, completed a Phase I, 25 patient clinical trial called CADUCEUS. In this study, 25 patients were enrolled who had suffered a heart attack within a mean of 65 days. 17 of those patients received CAP-1001 and the remaining eight patients received standard of care. 12 months after the study was completed, no measurable safety effects occurred in the 17 patients who were treated with CAP-1001. 16 of the 17 treated patients showed a mean reduction of approximately 45% in scar mass and an increase in viable heart muscle one-year post heart attack. The eight patients in the control group had no significant change in infarct (scar) size. At present, there is no plan for another clinical trial for CAP-1001. Capricor's strategy for further development of CAP-1001 will depend to a large degree on the outcome of its trials involving CAP-1002 and its ability to obtain significant capital to conduct further studies with CAP-1001.

*Exosomes* – Exosomes are nano-sized, membrane-enclosed vesicles, or “bubbles”, that are filled with select molecules, including proteins and microRNAs, which, when released, send messages to neighboring cells to regulate cellular functions. Capricor is currently in pre-clinical testing to explore the possible future therapeutic benefits that exosomes may possess.

*CU-NP* – Nile acquired the rights to CU-NP in September 2008. Prior to the merger between Capricor and Nile, Nile had incurred approximately \$0.7 million in expenses directly relating to the CU-NP development program through September 30, 2013. We are currently evaluating whether to proceed with further clinical development of this product.

*CSps* – This product candidate consists of multicellular clusters called cardiospheres. CSps are in pre-clinical development and have yet to be studied in humans. At present, there is no plan for a clinical trial of CSps.

Our expenditures on current and future clinical development programs, particularly our CAP-1002 and Cenderitide programs, are expected to be substantial and to increase in relation to our available capital resources. However, these planned expenditures are subject to many uncertainties, including the results of clinical trials and whether we develop any of our product candidates with a partner or independently. As a result, we cannot predict with any significant degree of certainty the amount of time which will be required to complete our clinical trials, the costs of completing research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during manufacturing and clinical development and as a result of a variety of other factors, including:

- the number of trials and studies in a clinical program;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;
- the costs of manufacturing our product candidates; and
- the costs, requirements and timing of, and the ability to secure, regulatory approvals.

*Grant Income.* Grant income for the three months ended March 31, 2015 and 2014 was approximately \$0.7 million and zero, respectively. This increase in grant income in the first quarter of 2015 as compared to 2014 is due to the timing of disbursements under our Phase IIB Bridge grant through the NIH for expenses incurred in the period ended March 31, 2015 compared to the period ended March 31, 2014, during which no expenses were incurred.

*Collaboration Income.* As a result of the Janssen Agreement, collaboration income for each of the three months ended March 31, 2015 and 2014 was approximately \$1.0 million. Since a ratable portion of the payment to Capricor was recognized over both periods under the terms of the Janssen Agreement, there is no change from period to period.

*Investment Income.* Investment income for the three months ended March 31, 2015 and 2014 was \$275 and \$153 respectively. This increase in investment income in the first quarter of 2015 as compared to the same period in 2014 is primarily due to an increased cash position and interest received.

*Interest Expense.* Interest expense for the three months ended March 31, 2015 and 2014 was \$61,681 and \$25,327, respectively. This increase in interest expense in the first quarter of 2015 as compared to the same period in 2014 is due to accrued interest on the CIRM loan award, related to the principal balance being higher in the first quarter of 2015, as compared to the same period of 2014.

## **Liquidity and Capital Resources**

The following table summarizes our liquidity and capital resources as of March 31, 2015 and as of December 31, 2014 and our net increase (decrease) in cash and cash equivalents for the three months ended March 31, 2015 and 2014, and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

Liquidity and capital resources	March	December
	31,	31, 2014

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	2015	
Cash and cash equivalents	\$6,939	\$ 8,035
Working Capital	\$17,875	\$ 5,308
Stockholders' equity (deficit)	\$7,325	\$ (6,249 )

	Three months ended March 31,	
	2015	2014
Cash flow data		
Cash provided by (used in):		
Operating activities	\$(2,052 )	\$11,343
Investing activities	(15,525)	(94 )
Financing activities	16,481	1
Net increase (decrease) in cash and cash equivalents	\$(1,096 )	\$11,250

Our total cash resources, not including restricted cash, as of March 31, 2015 were approximately \$6.9 million compared to approximately \$8.0 million as of December 31, 2014. The decrease in total cash resources from December 31, 2014 to March 31, 2015 is primarily due to an allocation of cash and cash equivalents to marketable securities. Total marketable securities, consisting primarily of United States treasuries, was approximately \$15.5 million as of March 31, 2015 as compared to zero as of December 31, 2014. The increase in working capital and stockholders' equity as of March 31, 2015 is primarily due to the approximately \$17.0 million received as a result of the two private placements of our common stock completed during the first quarter of fiscal year 2015. As of March 31, 2015, we had approximately \$20.1 million in total liabilities, of which approximately \$7.3 million was recorded as deferred income under the Janssen Agreement, and approximately \$17.9 million in net working capital. We incurred a net loss of approximately \$3.5 million for the three months ended March 31, 2015.

Cash used in operating activities was approximately \$2.1 million for the three months ended March 31, 2015 and cash provided by operating activities was approximately \$11.3 million for the three months ended March 31, 2014. The difference of approximately \$13.4 million in cash from operating activities is primarily due to our receipt of the \$12.5 million payment under the terms of the Janssen Agreement in early 2014. Additionally, there was an increase in total operating expenses for the three months ended March 31, 2015 of approximately \$3.0 million as compared to the same period of 2014. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, including as we expand our technology portfolio and engage in further research and development activities, and, in particular, conduct pre-clinical studies and clinical trials, we expect to continue incurring substantial and increasing losses, which will generate negative net cash flows from operating activities.

We had cash flow used in investing activities of approximately \$15.5 million for the three months ended March 31, 2015 and approximately \$0.1 million for the three months ended March 31, 2014. The difference in cash used in investing activities for the three months ended March 31, 2015 as compared to the same period of 2014 is primarily due to the purchase of marketable securities in the period ended March 31, 2015.

We had cash provided by financing activities of approximately \$16.5 million and \$933 for the three months ended March 31, 2015 and 2014, respectively. The difference in cash provided by financing activities for the three months ended March 31, 2015 as compared to the same period of 2014 is primarily a result of the two private placements of our common stock completed during the first quarter of fiscal year 2015.

Phase II of Capricor's ALLSTAR trial has been funded in large part through a loan award from CIRM. Subject to sufficient funding, following completion of the Phase II trial would be a Phase IIb and/or Phase III trial. If we continue with a Phase IIb and/or Phase III trial, we will need substantial additional capital in order to continue the development of CAP-1002. Pursuant to the Janssen Agreement, the chemistry, manufacturing and controls package will be developed by the joint efforts of Janssen and Capricor. Capricor will be required to reimburse Janssen for its costs of development up to an agreed-upon maximum amount. If Janssen exercises its exclusive option under the Janssen Agreement to enter into an exclusive license agreement with Capricor, Janssen will be responsible for any additional trials and future development costs with respect to CAP-1002.

We will need substantial additional capital in order to continue the development of Cenderitide. In March 2015, we completed enrollment of a Phase II clinical trial of Cenderitide. Depending on the outcome of the trial and the availability of resources, the Phase II clinical trial may be followed by an additional clinical study. In March 2011, the U.S. Food and Drug Administration, or the FDA, granted fast track designation to Cenderitide in the post-acute period. According to the FDA's website, fast track designation facilitates the development and expeditious review of drugs and biologics intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

Our research and development expenses will also increase as we further develop our exosomes program and if we conduct additional studies with CAP-1002, such as the second part of the DYNAMIC study and the development of CAP-1002 to treat Duchenne muscular dystrophy cardiomyopathy. In April 2015, Capricor was granted orphan drug designation by the FDA for CAP-1002 for the treatment of cardiomyopathy associated with DMD. Orphan drug designation is granted by the FDA Office of Orphan Drug Products to drugs intended to treat a rare disease or condition affecting fewer than 200,000 people in the U.S. This designation confers special incentives to the drug developer, including tax credits on the clinical development costs and prescription drug user fee waivers and may allow for a seven year period of market exclusivity in the U.S. upon FDA approval.

From inception through March 31, 2015, we financed our operations through private and public sales of our equity securities, NIH grants, a payment from Janssen and a CIRM loan award. In the first quarter of 2015, we completed two private placements, securing approximately \$17.0 million in additional capital through the issuance of common equity. As we have not generated any revenue from the sale of our products to date, and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital in order to fund our immediate general corporate activities and, thereafter, to fund our research and development, including our long-term plans for clinical trials and new product development. We may seek to raise additional funds through various potential sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, or if such funds are available to us, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that may not be favorable to us.

Our estimates regarding the sufficiency of our financial resources are based on assumptions that may prove to be wrong. We may need to obtain additional funds sooner than planned or in greater amounts than we currently anticipate. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the progress of our research activities;
- the number and scope of our research programs;



the progress of our pre-clinical and clinical development activities;  
the progress of the development efforts of parties with whom we have entered into research and development agreements;  
our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;  
the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and  
the costs and timing of regulatory approvals.

### ***Financing Activities by the Company***

***February 2015 Financing.*** On February 3, 2015, we entered into a Share Purchase Agreement with certain accredited investors, pursuant to which we agreed to issue and sell, in a private placement, or PIPE 2, to the PIPE 2 investors an aggregate of 1,658,822 shares of our common stock at a price per share of \$4.25 for an aggregate purchase price of approximately \$7,050,000.

In connection with PIPE 2, we entered into a Registration Rights Agreement with the investors in PIPE 2 on February 3, 2015. Pursuant to the terms of the Registration Rights Agreement for PIPE 2, we are obligated (i) to prepare and file with the Securities and Exchange Commission a registration statement to register for resale the shares issued and sold in PIPE 2, and (ii) to use our reasonable best efforts to cause the applicable registration statement to be declared effective by the Securities and Exchange Commission as soon as practicable, in each case subject to certain deadlines. We filed a Registration Statement on Form S-1, as may be amended from time to time (SEC File No. 333-202589), to register for resale the shares of common stock underlying the shares issued in PIPE 2, which such Registration Statement was declared effective by the Securities and Exchange Commission on March 30, 2015.

We may also be required to effect certain registrations to register for resale the shares issued and sold in PIPE 2 in connection with certain “piggy-back” registration rights granted to the PIPE 2 investors. We will be required to pay to each PIPE 2 investor liquidated damages equal to 1.0% of the aggregate purchase price paid by such investor pursuant to the PIPE 2 Share Purchase Agreement for the shares per month (up to a cap of 10.0%) if we do not meet certain obligations with respect to the registration of the shares, subject to certain conditions.

***January 2015 Financing.*** On January 9, 2015, we entered into a Share Purchase Agreement with select investors, pursuant to which we agreed to issue and sell to the investors, in a private placement, or PIPE 1 an aggregate of 2,839,045 shares of our common stock at a price per share of \$3.523 for an aggregate purchase price of approximately \$10,000,000.

In connection with PIPE 1, we also entered into a Registration Rights Agreement with the PIPE 1 investors on January 9, 2015. Pursuant to the terms of the Registration Rights Agreement, we are obligated (i) to prepare and file with the Securities and Exchange Commission a registration statement to register for resale the shares issued and sold in PIPE 1, and (ii) to use our reasonable best efforts to cause the applicable registration statement to be declared effective by the Securities and Exchange Commission as soon as practicable, in each case subject to certain deadlines. We filed a Registration Statement on Form S-1, as may be amended from time to time (SEC File No. 333-202589), to register for resale the shares of common stock underlying the shares issued in PIPE 1, which such Registration Statement was declared effective by the Securities and Exchange Commission on March 30, 2015.

We may also be required to effect certain registrations to register for resale the shares issued and sold in PIPE 1 in connection with certain “piggy-back” registration rights granted to the PIPE 1 investors. We will be required to pay to each PIPE 1 investor liquidated damages equal to 1.0% of the aggregate purchase price paid by such investor pursuant to the PIPE 1 Share Purchase Agreement for the shares per month (up to a cap of 10.0%) if we do not meet certain obligations with respect to the registration of the shares, subject to certain conditions.

On February 2, 2015, we entered into an amendment to the PIPE 1 Share Purchase Agreement with certain of the PIPE 1 investors, which amended certain provisions of such Share Purchase Agreement limiting our ability to issue additional shares of our common stock until the filing of an effective registration statement for the PIPE 1 shares. As a result of such amendment, the restriction on the issuance of additional shares was eliminated.

**March 2013 Financing.** On March 15, 2013, we entered into a convertible note purchase agreement with certain accredited investors pursuant to which we agreed to sell an aggregate principal amount of up to \$500,000 of secured convertible promissory notes, or the 2013 Notes, for an aggregate original issue price of \$425,000, representing a 15% original issue discount. The closing of the private placement also occurred on March 15, 2013, and resulted in the sale of 2013 Notes in the aggregate principal amount of \$450,000 for an aggregate original issue price of \$382,500.

On September 27, 2013, we and the holders of the 2013 Notes entered into an amendment to the 2013 Notes, which provided, among other things, that upon a Change of Control (as defined in the 2013 Notes), the conversion price applicable to the 2013 Notes and the exercise price applicable to the warrants issuable upon a Change of Control will be equal to the average dollar volume weighted average price, or VWAP, of our common stock for each trading day during the period from July 8, 2013 to September 30, 2013. The average VWAP during such period was approximately \$0.045 per share. Additionally, pursuant to the amendment, upon a conversion of the 2013 Notes in connection with a Change of Control, the holders confirmed that all obligations under the 2013 Notes would be deemed satisfied in full and released us from any claims relating to the 2013 Notes.

On October 21, 2013, we and the holders of the 2013 Notes entered into an amendment to the Convertible Note Purchase Agreement pursuant to which we sold to such holders additional notes having an aggregate principal amount of \$120,510, or the Additional Notes. The Additional Notes have identical terms and conditions as the 2013 Notes described above and were allocated among the holders on a pro rata basis based on their initial purchase of the 2013 Notes. In exchange for the issuance of the Additional Notes, we received aggregate gross proceeds of \$102,433. The 2013 Notes and the Additional Notes are collectively referred to herein as the 2013 Notes.

The 2013 Notes converted at the close of the merger between Capricor and Nile on November 20, 2013 into 251,044 shares of our common stock on a post-reverse stock split basis. Additionally, 251,044 warrants to purchase our common stock at a strike price of \$2.2725, on a post-reverse stock split basis, were issued to the holders of the 2013 Notes. We filed a Registration Statement on Form S-1, as amended from time to time (SEC File No. 333-195385), to register for resale the shares of common stock underlying the 2013 Notes, which such Registration Statement was declared effective by the Securities and Exchange Commission on June 6, 2014.

#### ***Financing Activities by Capricor, Inc.***

***CIRM Loan Agreement.*** On February 5, 2013, Capricor entered into a Loan Agreement with CIRM, or 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 the ALLSTAR clinical trial.

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 not discontinue the disbursement of funds. Capricor is in ongoing discussions with CIRM regarding the timing of the disbursements of funds in accordance with enrollment.

Under the terms of the CIRM Loan Agreement, CIRM deducted \$36,667 from the initial disbursement to cover its costs in conducting financial due diligence on Capricor. According to the original CIRM Loan Agreement, CIRM intended to also deduct approximately \$16,667 from each disbursement made in the second and third year of the loan period to cover its costs of continuing due diligence according to the payment disbursement schedule. However, in

June 2014, the CIRM Loan Agreement was amended to adjust the due diligence costs which can be deducted from the disbursements. CIRM refunded approximately \$6,667 to Capricor, which amount CIRM had previously withheld, and CIRM will not be permitted to withhold additional funds from the indirect costs portion of Capricor's future disbursements. So long as Capricor is not in default under the terms of the CIRM Loan Agreement, the loan may be forgiven during the term of the project period if Capricor abandons the trial due to the occurrence of a no-go milestone. After the end of the project period, the loan may also be forgiven if Capricor elects to abandon the project under certain circumstances. Under the terms of the CIRM Loan Agreement, Capricor is required to meet certain financial milestones by demonstrating to CIRM prior to each disbursement of loan proceeds that it has sufficient funds available to cover all costs and expenses anticipated to be required to continue Phase II of the ALLSTAR trial for at least the following 12-month period, less the costs budgeted to be covered by planned loan disbursements. Capricor did not issue stock, warrants or other equity to CIRM in connection with this award.

The timing of the distribution of funds pursuant to the CIRM Loan Agreement is contingent upon the availability of funds in the California Stem Cell Research and Cures Fund in the California State Treasury, as determined by CIRM in its sole discretion. Disbursements from time to time may be delayed or suspended in order to coincide with projected expenditures and patient enrollment.

#### *Grant Award*

On August 21, 2013, Capricor was approved for a Phase IIB Bridge grant through the NIH Small Business Innovation Research, or SBIR, program for continued development of its CAP-1002 product candidate. Under the terms of the grant, approximately \$2,879,437 will be disbursed to us over a period of three years, subject to annual and quarterly reporting requirements. In June 2014, Capricor received approval from the NIH to deploy this grant to fund the first part of the DYNAMIC trial. The first part of the DYNAMIC trial used CAP-1002 to treat patients with advanced heart failure. As of March 31, 2015, approximately \$1.4 million had been incurred under the terms of the award.

### **Off -Balance Sheet Arrangements**

There were no off-balance sheet arrangements as described by Item 303(a)(4) of Regulation S-K as of March 31, 2015.

### **Critical Accounting Policies and Estimates**

Our financial statements are prepared in accordance with generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis, including research and development and clinical trial accruals, and stock-based compensation estimates. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Our actual results could differ from these estimates. We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our financial statements and accompanying notes.

#### ***Grant Income***

The determination as to when income is earned is dependent on the language in each specific grant. Generally, we recognize grant income in the period in which the expense is incurred for those expenses that are deemed reimbursable under the terms of the grant.

#### ***Income from Collaborative 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 us is recognized when such amounts are earned. If we have continuing obligations to perform under the arrangement, such fees are recognized over the estimated period of the continuing performance obligation.

We account for multiple element arrangements, such as license and development agreements in which a customer may purchase several deliverables, in accordance with the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Subtopic 605-25, *Multiple Element Arrangements*. For new or materially amended

multiple element arrangements, we identify 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 our control. We allocate revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, we determine 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 we use 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.

We determined the deliverables under our Collaboration Agreement with Janssen did not meet the criteria to be considered separate accounting units for the purposes of revenue recognition. As a result, we recognized revenue from non-refundable, upfront fees ratably over the term of our performance under the agreement. 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 consolidated balance sheets and amortized over the estimated period of performance. We periodically review the estimated performance period of our contract based on the progress of our project.

#### ***Research and Development Expenses and Accruals***

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs, supplies, clinical trial costs, patient treatment costs, consulting fees, costs of personnel and supplies for manufacturing, costs of service providers for pre-clinical, clinical and manufacturing, and certain legal expenses resulting from intellectual property prosecution, stock compensation expense and other expenses relating to the design, development, testing and enhancement of our product candidates. Except for certain capitalized intangible assets, R&D costs are expensed as incurred.

Our cost accruals for clinical trials and other R&D activities are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and Contract Research Organizations, or CROs, clinical study sites, laboratories, consultants or other clinical trial vendors that perform activities in connection with a trial. Related contracts vary significantly in length and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of fixed, variable and capped amounts. Activity levels are monitored through close communication with the CROs and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CRO and significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter for each individual trial. These estimates are reviewed and discussed with the CRO or vendor as necessary, and are included in R&D expenses for the related period. For clinical study sites which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrollment in each quarter. All estimates may differ significantly from the actual amount subsequently invoiced, which may occur several months after the related services were performed.

In the normal course of business, we contract with third parties to perform various R&D activities in the on-going development of our product candidates. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of the accrual policy is to match the recording of expenses in the financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials and other R&D activities are recognized based on our estimates of the degree of completion of the event or events specified in the applicable contract.

No adjustments for material changes in estimates have been recognized in any period presented.

### ***Stock-Based Compensation***

Our results include non-cash compensation expense as a result of the issuance of stock, stock options and warrants, as applicable. We have issued stock options to employees, directors and consultants under our four stock option plans: (i) the Amended and Restated 2005 Stock Option Plan, (ii) the 2006 Stock Option Plan, (iii) the 2012 Restated Equity Incentive Plan (which superseded the 2006 Stock Option Plan), and (iv) the 2012 Non-Employee Director Stock Option Plan.

We expense the fair value of stock-based compensation over the vesting period. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. This valuation model requires us to make assumptions and judgments about the variables used in the calculation. These

variables and assumptions include the weighted-average period of time that the options granted are expected to be outstanding, the volatility of our common stock, the risk-free interest rate and the estimated rate of forfeitures of unvested stock options.

Stock options or other equity instruments to non-employees (including consultants) issued as consideration for goods or services received by us are accounted for based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). The fair value of stock options is determined using the Black-Scholes option-pricing model and is periodically re-measured as the underlying options vest. The fair value of any options issued to non-employees is recorded as expense over the applicable service periods.

The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial and development performance. Stock-based compensation expense is included in general and administrative expense or research and development expense, as applicable, in the Statements of Operations. We expect to record additional non-cash compensation expense in the future, which may be significant.

#### ***Warrant Liability***

We previously accounted for the warrants issued in connection with the April 2012 financing and the embedded derivative warrant liability contained in the 2013 Notes in accordance with the guidance on Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, which provides that we classify the warrant instrument as a liability at its fair value and adjust the instrument to fair value at each reporting period. 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. The 2013 Notes converted into shares of Company common stock and additional warrants for Company common stock were issued to the holders. Management has determined the value of the warrant liability to be insignificant at March 31, 2015, and no such liability has been reflected on the consolidated balance sheet.



### ***Long-Term Debt***

Capricor accounts for the loan proceeds under its CIRM Loan Agreement as long-term liabilities. Capricor recognizes the CIRM loan disbursements as a loan payable as the principal is disbursed rather than recognizing the full amount of the award. Capricor recognizes the disbursements in this manner since the period in which the loan will be paid back will not be in the foreseeable future. The terms of the CIRM Loan Agreement contain certain forgiveness provisions that may allow for the principal and interest of the loan to be forgiven. The potential for forgiveness of the loan is contingent upon many conditions, some of which are outside of Capricor's control, and no such estimates are made to determine a value for this potential for forgiveness.

### ***Restricted Cash***

Capricor accounts for the disbursements received under the CIRM Loan Agreement which have not been attributed to a particular project's costs through the current period as restricted cash. Generally, a reduction of restricted cash occurs when the Company deems certain costs are attributable to the ALLSTAR clinical trial.

### ***Recently Issued or Newly Adopted 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 generally accepted accounting principles in the United States of America ("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, 2016, 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. We are currently evaluating the effect that ASU 2014-09 will have on our condensed consolidated financial statement presentation or disclosures.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission, 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, 2014, as filed with the Securities and Exchange Commission on March 16, 2015.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

*Interest Rate Sensitivity*

Our exposure to market risk for changes in interest rates relates primarily to our marketable securities and cash and cash equivalents. As of March 31, 2015, the fair value of our cash, cash equivalents, including restricted cash, and our marketable securities was approximately \$24.5 million. Additionally, as of March 31, 2015, Capricor's portfolio was classified as cash, cash equivalents and marketable securities, which consist primarily of money market funds and bank money market, which included short term United States treasuries, bank savings and checking accounts. Capricor did not have any investments with significant exposure to the subprime mortgage market issues.

The goal of our investment policy is to place our investments with highly rated credit issuers and limit the amount of credit exposure. We seek to improve the safety and likelihood of preservation of our invested funds by limiting default risk and market risk. Our investments may be exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments, if any. We will manage this exposure by performing ongoing evaluations of our investments. Due to the short-term maturities, if any, of our investments to date, their carrying value has always approximated their fair value. Our policy is to mitigate default risk by investing in high credit quality securities, and we currently do not hedge interest rate exposure. Due to our policy of making investments in United States treasury securities with primarily short-term maturities, we believe that the fair value of our investment portfolio would not be significantly impacted by a hypothetical 100 basis point increase or decrease in interest rates.

**Item 4. Controls and Procedures.**

We have adopted and maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that controls and procedures, no matter how well designed and operated, cannot provide absolute assurance of achieving the desired control objectives.

As required by Rules 13a-15(b) and 15d-15(b) of the Securities Exchange Act of 1934, as amended, we carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Principal Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Principal Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level.

***Changes in Internal Controls over Financial Reporting***

There has been no change in our internal control over financial reporting during the period ended March 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II — OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

We are not a party to any material pending legal proceedings.

### **Item 1A. Risk Factors.**

There have been no material changes in our risk factors from those previously disclosed in Part 1, Item 1A, “Risk Factors,” of our Annual Report on Form 10-K for the year ended December 31, 2014 that was filed with the Securities and Exchange Commission on March 16, 2015.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

On January 9, 2015, the Company entered into a Share Purchase Agreement with select investors pursuant to which the Company agreed to issue and sell to the investors, in a private placement (“PIPE 1”), an aggregate of 2,839,045 shares of its common stock at a price per share of \$3.523 for an aggregate purchase price of approximately \$10,000,000. The shares of common stock sold in PIPE 1 were issued and sold in reliance on the exemption from registration afforded by Section 4(2) of the Securities Act of 1933, as amended (the “Securities Act”), and Rule 506 of Regulation D promulgated under the Securities Act and corresponding provisions of state securities or “blue sky” laws. Each of the investors in PIPE 1 represented to the Company that it was acquiring the shares for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof.

On February 3, 2015, the Company entered into a Share Purchase Agreement with certain accredited investors, pursuant to which the Company agreed to issue and sell to the investors, in a private placement (“PIPE 2”), an aggregate of 1,658,822 shares of its common stock, par value \$0.001 per share, at a price per share of \$4.25 for an aggregate purchase price of approximately \$7,050,000. The shares of common stock sold in PIPE 2 were issued and sold to “accredited investors,” as that term is defined in the Securities Act, and in reliance on the exemption from registration afforded by Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act and corresponding provisions of state securities or “blue sky” laws. Each of the investors in PIPE 2 represented to the Company that it was acquiring the shares for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof.

**Item 3. Defaults Upon Senior Securities.**

Not applicable.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

- 3.1 Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on February 9, 2007).
- 3.2 Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on November 26, 2013).
- 3.3 Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the Commission on February 9, 2007).
- 4.1 Warrant Agreement, dated April 21, 2010, between the Company and American Stock Transfer & Trust Company, LLC, as Warrant Agent (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on April 22, 2010).
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- 4.3 Form of Representative's Warrant issued to Maxim Group, LLC in connection with April 2010 Public Offering (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K, filed with the Commission on April 22, 2010).
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- 10.1 Share Purchase Agreement, dated as of January 9, 2015, by and among Capricor Therapeutics, Inc. and the Investors (incorporated by reference to Exhibit 10.1 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on January 22, 2015).

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10.6 First Amendment to Exclusive License Agreement, dated as of February 27, 2015, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.54 to the Company's Registration Statement on Form S-1 (File No. 333-202589), filed with the Commission on March 6, 2015). +

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- 31.1 Certification of Chief Executive Officer pursuant to Securities Exchange Act Rule 13a-15(e)/15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 31.2 Certification of Principal Financial Officer pursuant to Securities Exchange Act Rule 13a-15(e)/15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*
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The following financial information from Capricor Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2015 formatted in eXtensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014, (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2015 and March 31, 2014, (iii) Condensed Consolidated Statement of Stockholders' Equity (Deficit) for the period from December 31, 2014 through March 31, 2015, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and March 31, 2014, and (v) Notes to Condensed Consolidated Financial Statements.\*

\* Filed herewith.

+ The Company has received confidential treatment with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

**SIGNATURES**

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 thereunto duly authorized.

**CAPRICOR THERAPEUTICS, INC.**

Date: May 12, 2015 By: /s/ Linda Marbán, Ph.D.  
Linda Marbán, Ph.D.  
Chief Executive Officer  
(Principal Executive Officer)

Date: May 12, 2015 By: /s/ Anthony Bergmann  
Anthony Bergmann  
Vice President of Finance  
(Principal Financial and Accounting Officer)

## EXHIBIT INDEX

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