CAPRICOR THERAPEUTICS, INC.
Form 10-Q
November 14, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2014

or

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

For the transition period from to

Commission File Number: 001-34058

CAPRICOR THERAPEUTICS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

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

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

(Address of principal executive offices)

90211

(Zip Code)

(310) 358-3200
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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Special Note Regarding Forward-Looking Statements

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

- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- expectation of or dates for commencement of clinical trials, IND filings, similar plans or projections;
- the regulatory approval of our drug candidates;
- our use of clinical research centers, third party manufacturers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- our ability to manufacture products for clinical and commercial use;
- our ability to protect our patents and other intellectual property;
- our ability to market any of our products;
- our history of operating losses;
- our ability to secure adequate protection for our intellectual property;
- our ability to compete against other companies and research institutions;

- the effect of potential strategic transactions on our business;
- acceptance of our products by doctors, patients or payors and the availability of reimbursement for our product candidates;
- our ability to attract and retain key personnel; and
- the volatility of our stock price.

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

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

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

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

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements.

CAPRICOR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

ASSETS

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

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

See accompanying notes to the unaudited condensed consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

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

See accompanying notes to the unaudited condensed consolidated financial statements.

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CAPRICOR THERAPEUTICS, INC.

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

(unaudited)

	COMMON STOCK					
	SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE LOSS	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE	TOTAL STOCKHOLDERS' EQUITY (DEFICIT)
Balance at December 31, 2013	11,687,747	$ 11,687	$ 15,552,946	$ (980)	$ (16,098,535)	$ (534,882)
Stock-based compensation	1,666	2	347,480	-	-	347,482
Unrealized loss on marketable securities	-	-	-	(627)	-	(627)
Stock options and awards	14,361	15	4,584	-	-	4,599
Net loss	-	-	-	-	(4,288,537)	(4,288,537)
Balance at September 30, 2014	11,703,774	$ 11,704	$ 15,905,010	$ (1,607)	$ (20,387,072)	$ (4,471,965)

See accompanying notes to the unaudited condensed consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

	Nine months ended September 30,	
	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(4,288,537)	$(4,586,940)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	28,352	20,387
Stock-based compensation	347,482	177,792
Change in assets - (increase) decrease:		
Restricted cash	(2,297,801)	(3,067,799)
Grants receivable	(259,800)	643,368
Interest receivable	(636)	21,788
Prepaid expenses and other current assets	117,663	16,803
Deposits	(29,592)	(7,640)
Change in liabilities - increase (decrease):		
Accounts payable and accrued expenses	106,557	453,780
Accounts payable and accrued expenses, related party	(81,287)	37,380
Sub-award payable, related party	(41,855)	(53,567)
Accrued royalties	(10,765)	(12,452)
Accrued interest	140,122	33,275
Deferred revenue	9,374,999	-
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES	3,104,902	(6,323,825)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	-	(226,998)
Proceeds from sales and maturities of marketable securities	549	2,818,740
Payments for purchase of property and equipment	(146,685)	(52,321)
Purchase of leasehold improvements	(23,744)	-
Payments for patents	(64,514)	(36,810)
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	(234,394)	2,502,611
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock	-	1,812
Proceeds from loan payable, net	5,200,791	3,925,066
Proceeds from stock options and awards	4,599	-

NET CASH PROVIDED BY FINANCING ACTIVITIES	5,205,390	3,926,878
NET INCREASE IN CASH AND CASH EQUIVALENTS	8,075,898	105,664
Cash and cash equivalents balance at beginning of period	1,729,537	170,106
Cash and cash equivalents balance at end of period	$9,805,435	$275,770
SUPPLEMENTAL DISCLOSURES:		
Interest paid in cash	$-	$-
Income taxes paid in cash	$-	$-

See accompanying notes to the unaudited condensed consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.

Notes to CONDENSED CONSOLIDATED financial statements

(unaudited)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

The mission of Capricor Therapeutics, Inc., a Delaware corporation (referred to herein as "Capricor Therapeutics" or the "Company"), is to improve the treatment of diseases by commercializing innovative therapies, 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 31, 2014, from which the December 31, 2013 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, 2014.

Consummation of 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 (as amended, the "Merger Agreement"), by and among Nile, Bovet Merger Corp., a Delaware corporation and a wholly-owned subsidiary of Nile ("Merger Sub"), and Capricor, Merger Sub merged with and into Capricor and Capricor became a wholly-owned subsidiary of Nile (the "Merger"). Immediately prior to the effective time of the Merger (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 (the "Reverse Stock Split"), (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. At the Effective Time and in connection with the Merger, each outstanding share of Capricor's Series A-1, Series A-2 and Series A-3 Preferred Stock was converted into one share of common stock, par value $0.001 per share, of Capricor (the "Capricor Common Stock").

As a result of the Merger and in accordance with the terms of the Merger Agreement, each outstanding share of Capricor Common Stock was converted into the right to receive approximately 2.07 shares of the common stock of Capricor Therapeutics, par value $0.001 per share (the "Capricor Therapeutics Common Stock"), on a post 1-for-50 Reverse Stock Split basis. Immediately after the Effective Time and in accordance with the terms of the Merger Agreement, the former Capricor stockholders owned approximately 90% of the outstanding common stock of Capricor Therapeutics, and the Nile stockholders owned approximately 10% of the outstanding common stock of Capricor Therapeutics, in each case on a fully-diluted basis. For accounting purposes, the Merger is accounted for as a reverse merger with Capricor as the accounting acquiror (legal acquiree) and Nile as the accounting acquiree (legal acquiror).

Since Capricor was deemed to be the accounting acquiror in the Merger, the historical financial information for periods prior to the Merger reflect the financial information and activities solely of Capricor and not of Nile. The historical equity of Capricor has been retroactively adjusted to reflect the equity structure of Capricor Therapeutics using the exchange ratio established in the Merger, which reflects the number of shares Capricor Therapeutics issued to equity holders of Capricor as a result of the Merger. The retroactive adjustment of Capricor's equity includes Capricor's preferred stock as if such shares of preferred stock had been converted into Capricor Common Stock at the respective dates of issuance, which is consistent with the terms of the Merger. Accordingly, all common and preferred shares and per share amounts for all periods presented in the condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q and condensed consolidated notes thereto have been adjusted retrospectively, where applicable, to reflect the respective exchange ratio established in the Merger.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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

After the Effective Time, each then outstanding Capricor stock option, whether vested or unvested, was assumed by Capricor Therapeutics in accordance with the terms of (i) the 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan, or (iii) the 2012 Non-Employee Director Stock Option Plan, as applicable, and the stock option agreement under which each such option was issued. All rights with respect to Capricor Common Stock under outstanding Capricor options were converted into rights with respect to Capricor Therapeutics Common Stock.

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 September 30, 2014 were approximately $10.1 million, compared to $2.1 million as of December 31, 2013. 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. 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, as well as

government-funded grants and/or loans.

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.

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 September 30, 2014 and December 31, 2013, restricted cash represents funds received under Capricor's Loan Agreement with CIRM (see Note 2 – "Loan Payable"), which are to be allocated to the ALLSTAR clinical trial research costs as incurred.

Marketable Securities

At September 30, 2014 and December 31, 2013, marketable securities consisted primarily of United States treasuries. These investments are considered available-for-sale. Realized gains and losses on the sale of debt and equity securities are determined on the specific identification method. Unrealized gains and losses are presented as other comprehensive income (loss).

Intangible Assets

As a result of the Merger, the Company recorded $1.5 million as in-process research and development, a component of intangible assets. As of September 30, 2014, the Company had not begun amortizing the in-process research and development.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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

Government Research Grants

Government research grants that provide funding for research and development activities are recognized as income when the related expenses are incurred, as applicable.

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 Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("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.

Goodwill

The Company calculates goodwill as the difference between the acquisition date fair value of the estimated consideration paid in the Merger and the values assigned to the assets acquired and liabilities assumed. Goodwill is not amortized but is generally subject to an impairment test annually or more frequently if an event or circumstance indicates that an impairment loss may have been incurred. The Company determined the goodwill balance of $1.9 million to be impaired as of December 31, 2013, and charged such amount to other expenses.

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 $2.0 million and $1.0 million for the three months ended September 30, 2014 and 2013, respectively, and approximately $5.2 million and $3.5 million for the nine months ended September 30, 2014 and 2013, respectively.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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

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 $1.5 million for both the three months ended September 30, 2014 and 2013. For the nine months ended September 30, 2014 and 2013, the Company's comprehensive loss was approximately $4.3 million and $4.6 million, respectively. The Company's other comprehensive income (loss) is related to a net unrealized gain (loss) on marketable securities. For the three months ended September 30, 2014 and 2013, the Company's other comprehensive gain (loss) was $(733) and $30,141, respectively. For the nine months ended September 30, 2014 and 2013, the Company's other comprehensive gain (loss) was $(627) and $18,819, 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 warrants issued to third parties, have been excluded from the diluted loss per share calculation because their effect is anti-dilutive.

For the three months ended September 30, 2014 and 2013, warrants and options to purchase 5,311,693 and 6,463,932 shares, respectively, have been excluded from the computation of potentially dilutive securities. For the nine months ended September 30, 2014 and 2013, warrants and options to purchase 5,311,693 and 6,463,932 shares, 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 September 30, 2014 and December 31, 2013 for assets and liabilities measured at fair value on a recurring basis:

	September 30, 2014			
	Level I	Level II	Level III	Total
Marketable securities	$325,318	$ -	$ -	$325,318

	December 31, 2013			
	Level I	Level II	Level III	Total
Marketable securities	$326,494	$ -	$ -	$326,494

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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

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

Warrant Liability

The Company accounts for some of its warrants issued in accordance with the guidance on Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, which provides that the Company must classify the warrant instrument as a liability at its fair value and adjust the instrument to fair value at each reporting period. The fair value of warrants is estimated by management using the Black-Scholes option-pricing model. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized as a component of other income or expense. Prior to the Merger, the Company and holders of warrants to purchase shares of common stock entered into agreements pursuant to which such holders agreed to receive an aggregate of 59,546 shares of the Company's common stock in exchange for the cancellation and surrender of their warrants. No proceeds were received by the Company from these issuances. Management has determined the value of the warrant liability to be insignificant at September 30, 2014, and no such liability has been reflected on the balance sheet.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"). ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current U.S. GAAP and replace it with a principle-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or

services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for reporting periods beginning after December 15, 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. The Company is currently evaluating the effect that the adoption of ASU 2014-09 will have on the Company's condensed consolidated financial statements.

In June 2014, the FASB issued ASU 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance* ("ASU 2014-10"), which eliminates the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. Additionally, ASU 2014-10 eliminates the separate requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flow and shareholders' equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. ASU 2014-10 is effective for fiscal years beginning after December 15, 2014 and interim periods therein, with early adoption permitted. The Company adopted this guidance in the second quarter of fiscal year 2014 on a prospective basis.

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, 2013, as filed with the Securities and Exchange Commission on March 31, 2014.

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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

2. LOAN PAYABLE (Continued)

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. 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 $6,667 to Capricor, which amount CIRM had previously withheld, and, going forward, 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.

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.

Capricor did not issue stock, warrants or other equity to CIRM in connection with this award. The due diligence costs to be deducted from each disbursement are recorded as a discount on the loan and amortized to general and administrative expenses over the remaining term of the loan. As of September 30, 2014, $30,000 of loan costs were

capitalized with the balance of $18,243 to be amortized over the next 3.4 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 September 30, 2014 and 2013, interest expense under the CIRM loan was $60,091 and $23,353, respectively. For the nine months ended September 30, 2014 and 2013, interest expense under the CIRM loan was $140,122 and $33,275, respectively.

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.

Outstanding Shares

At September 30, 2014, the Company had 11,703,774 shares of common stock issued and outstanding.

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CAPRICOR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

3. STOCKHOLDERS' EQUITY (Continued)

Conversion of all Convertible Preferred Stock at the Merger

Prior to the Merger and without giving effect to the applicable multiplier, Capricor was authorized to issue 5,426,844 shares of convertible preferred stock, which was allocated as follows: Series A-1: 940,000 shares, all of which were issued; Series A-2: 736,844 shares, all of which were issued; and Series A-3: 3,750,000 shares, of which 1,500,000 shares were issued. During 2011 and 2012, the 1,500,000 shares of Series A-3 convertible preferred stock, with a par value of $0.001 per share, were issued for cash proceeds of $6,000,000. Immediately prior to the Effective Time, all shares of Capricor preferred stock were converted into shares of Capricor common stock pursuant to the terms of the Merger Agreement. The shares of Capricor preferred stock that were converted into Capricor common stock, as a result of the Merger and in accordance with the terms of the Merger Agreement, were exchanged according to the applicable multiplier for 6,591,494 shares of common stock of the Company, and all rights and preferences (including dividends) attached to the shares of Capricor preferred stock were rendered void. The preferred shares are presented retrospectively as shares of common stock on an as-converted to common stock basis.

4. STOCK AWARDS, WARRANTS AND OPTIONS

Warrants

The following table summarizes all warrant activity for the period ended September 30, 2014:

	Warrants	Weighted Average Exercise Price
Outstanding at January 1, 2014	332,281	$ 17.20
Granted	-	-

Exercised	-	-
Expired	(28,400)	94.00
Outstanding at September 30, 2014	303,881	$ 10.02

The following table summarizes all outstanding warrants to purchase shares of the Company's common stock as of September 30, 2014:

At September 30, 2014			
Grant Date	Warrants Outstanding	Range of Exercise Prices	Expiration Date
4/21/2010	52,650	$ 47.00	4/20/2015
4/4/2012	187	$ 2.27	4/3/2017
11/20/2013	251,044	$ 2.27	11/19/2018
	303,881		

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. During the nine months ended September 30, 2014, the Company issued 1,666 shares of that restricted common stock grant, which were valued at approximately $6,789. The fair value of the restricted stock was determined using the Company's closing stock price on the vesting date. This restricted stock grant vests monthly over a period of one year.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

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 Stock 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 (after the effects of the Reverse Stock Split at the consummation of the Merger). 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 the Merger 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 the Merger 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 September 30, 2014 and 2013 were approximately $3.83 and $0.26 per share, respectively.

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 September 30, 2014 and 2013:

	September 30, 2014	September 30, 2013
Expected volatility	112%	100%
Expected term	7 years	6-7 years
Dividend yield	0%	0%
Risk-free interest rates	2.15%	0.77% - 1.39%

Employee stock-based compensation expense for the three and nine months ended September 30, 2014 and 2013 was as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
General and administrative	$113,690	$71,641	$274,496	$177,792
Research and development	34,797	-	66,197	-
Total	$148,487	$71,641	$340,693	$177,792

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

As of September 30, 2014, the total unrecognized fair value compensation cost related to non-vested stock options was approximately $1.8 million, which is expected to be recognized over approximately 4 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 nine months ended September 30, 2014:

	Number of Options	Weighted Average Exercise Price
Outstanding at January 1, 2014	4,888,519	$ 0.51
Granted	368,154	5.01
Exercised	(14,361)	0.32
Expired/Cancelled	(234,500)	2.41
Outstanding at September 30, 2014	5,007,812	$ 0.75
Exercisable at September 30, 2014	3,008,756	$ 0.47

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 September 30, 2014, the Company maintained approximately $13.6 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 is $16,620 per month for the first twelve months of the term and will increase to $17,285 per month for the second twelve months of the term. 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 is approximately $15,461 per month for the first six months of the term and will increase 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 September 30, 2014 are as follows:

Years ended	Operating Leases
2014	$69,381
2015	335,910
2016	232,200
2017	96,750
Total minimum lease payments	$734,241

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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6. COMMITMENTS AND CONTINGENCIES (Continued)

Expense incurred under operating leases to unrelated parties was approximately $51,855 and $49,860 for the three months ended September 30, 2014 and 2013, respectively, and $151,575 and $104,460 for the nine months ended September 30, 2014 and 2013, respectively. Expense incurred under operating leases to related parties was approximately $46,382 and $13,662 for the three months ended September 30, 2014 and 2013, respectively, and $84,613 and $40,986 for the nine months ended September 30, 2014 and 2013, 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 September 30, 2014.

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.

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.

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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

7. LICENSE AGREEMENTS (Continued)

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 September 30, 2014, $100,000 was accrued due to the fact that Phase I of the ALLSTAR study enrollment had been completed.

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 is 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.

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.

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.

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CAPRICOR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

7. LICENSE AGREEMENTS (Continued)

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.

As noted in this Quarterly Report on Form 10-Q, 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 and the Co-Founder of Capricor, and Scientific Advisory Board Chairman of Capricor.

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's 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") and a Clinical Trial Funding Agreement with Medtronic, Inc. ("Medtronic"), which also includes 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 Securities and Exchange Commission (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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

7. LICENSE AGREEMENTS (Continued)

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 (i) the expiration of the last to expire valid claim contained in the Mayo patents, or (ii) 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. The Company may terminate the Amended Mayo Agreement without cause upon 90 days'

written notice.

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. Nile received the final reimbursement of $195,500 in February 2012 and a total of $1,550,000 over the life of the agreement. 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 under Note 9 - "Subsequent Events".

8. RELATED PARTY TRANSACTIONS

Lease and Sub-Lease Agreements

As noted in this Quarterly Report on Form 10-Q, 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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

8. RELATED PARTY TRANSACTIONS (Continued)

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 September 30, 2014 and 2013, Capricor recognized $7,500 in sublease income from the related party. For each of the nine-month periods ended September 30, 2014 and 2013, Capricor recognized $22,500 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.

Sub-Award Agreement

Effective January 30, 2012, Capricor entered into a sub-award agreement with CSMC. At September 30, 2014 and December 31, 2013, the Company had sub-award amounts payable to CSMC totaling $0 and $41,855, respectively. At September 30, 2014, the Company did not have any sub-award amounts payable as the award agreement with CSMC ended pursuant to its terms.

Payables to Related Party

At September 30, 2014 and December 31, 2013, the Company had accounts payable and accrued expenses, which excludes the sub-award amounts payable, to CSMC totaling $300,855 and $382,142, respectively.

9. SUBSEQUENT EVENTS

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 Capricor 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 Capricor ("Natriuretic Peptide Patents"). Under the Transfer Agreement, Capricor 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 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 has the right to terminate the Transfer Agreement and to have the rights to the Natriuretic Peptide Patents reassigned to it by Capricor if either Capricor, an affiliate, or a non-party licensee fails to commence a clinical trial of a CD-NP product within 18 months from the effective date.

In the event of a termination of the Transfer Agreement, (i) the Natriuretic Peptide Patents which were not owned or co-owned by Capricor prior to the effective date of the Transfer Agreement shall be assigned back to Medtronic; (ii) Capricor's rights in the Natriuretic Peptide Patents that were co-owned by Capricor pursuant to the Clinical Trial Funding Agreement will remain with Capricor, subject to the surviving terms and provisions thereof; and (iii) Capricor 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 Capricor 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 Capricor 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 Capricor upon the achievement of certain defined milestones, which payments, in the aggregate, total up to $7.0 million.

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CAPRICOR THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

9. SUBSEQUENT EVENTS (Continued)

Capricor expects to file the Transfer Agreement as an exhibit to its next filing in which the Transfer Agreement is required to be included, and intends to seek confidential treatment for certain terms and provisions of the Transfer Agreement. The foregoing description is a summary of the material terms of the Agreement, does not purport to be complete, and is qualified in its entirety by reference to the text of the Transfer Agreement when filed.

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., 2nd Floor, Beverly Hills, California 90211. Our telephone number is (310) 358-3200 and our Internet address is *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, 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.

At the Effective Time and in connection with the merger between Capricor and Nile, each outstanding share of Capricor's Series A-1, Series A-2 and Series A-3 Preferred Stock was converted into one share of common stock, par

value $0.001 per share, of Capricor.

As a result of the merger between Capricor and Nile and in accordance with the terms of the Merger Agreement, each outstanding share of Capricor common stock was converted into the right to receive approximately 2.07 shares of the common stock of Capricor Therapeutics, par value $0.001 per share, on a post 1-for-50 reverse stock split basis. Immediately after the Effective Time and in accordance with the terms of the Merger Agreement, the former Capricor stockholders owned approximately 90% of the outstanding common stock of Capricor Therapeutics, and the Nile stockholders owned approximately 10% of the outstanding common stock of Capricor Therapeutics, in each case on a fully-diluted basis. For accounting purposes, the merger between Capricor and Nile is accounted for as a reverse merger with Capricor as the accounting acquiror (legal acquiree) and Nile as the accounting acquiree (legal acquiror).

After the Effective Time, each then outstanding Capricor stock option, whether vested or unvested, was assumed by Capricor Therapeutics in accordance with the terms of the (i) 2006 Stock Option Plan, (ii) 2012 Restated Equity Incentive Plan, or (iii) 2012 Non-Employee Director Stock Option Plan, as applicable, and the stock option agreement under which each such option was issued. All rights with respect to Capricor common stock under outstanding Capricor options were converted into rights with respect to Capricor Therapeutics common stock.

Since Capricor was deemed to be the accounting acquiror in the merger, the historical financial information for periods prior to the merger reflects the financial information and activities solely of Capricor and not of Nile. The historical equity of Capricor has been retroactively adjusted to reflect the equity structure of Capricor Therapeutics using the respective exchange ratio established in the merger between Capricor and Nile, which reflects the number of shares Capricor Therapeutics issued to equity holders of Capricor as a result of the merger. The retroactive adjustment of Capricor’s equity includes Capricor’s preferred stock as if such shares of preferred stock had been converted into Capricor common stock at the respective dates of issuance, which is consistent with the terms of the merger. Accordingly, all common and preferred shares and per share amounts for all periods presented in the condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q and condensed consolidated notes thereto have been adjusted retrospectively, where applicable, to reflect the respective exchange ratio established in the merger.

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 I/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 improvements 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 improvements. Additional Phase I data will be presented at the AHA in November 2014 with a more complete data set.

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. 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 ALLSTAR is being funded in large part through the support of the California Institute for Regenerative Medicine, or CIRM.

Recently, 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.

Additionally, Capricor has been awarded a grant for approximately $3.0 million from the NIH to support further development of the CAP-1002 product. Capricor also received authorization to begin clinical investigations from the U.S. Food and Drug Administration, or the FDA, on an investigational new drug, or IND, for a trial named "DYNAMIC" (dilated cardiomyopathy intervention with allogeneic myocardially-regenerative cells). In June 2014, Capricor received approval from the NIH to use the funds from the grant for the Phase I portion of the DYNAMIC trial, which will be sponsored by Capricor. The Company intends that the Phase I portion of the DYNAMIC trial will

use CAP-1002 to treat patients with advanced heart failure.

Furthermore, in October 2014, Capricor announced plans to pursue a clinical program for the treatment of Duchenne Muscular Dystrophy, or DMD, with CAP-1002. The planned clinical program will aim to treat cardiac dysfunction associated with the disease. Capricor is planning to seek an IND based, in part, on data findings from the laboratory of Dr. Eduardo Marbán. If an IND is received, Capricor is planning to initiate a Phase I clinical trial in 2015.

- **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 8 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.

- **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.

- **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. Capricor is currently in pre-clinical testing to explore the possible future therapeutic benefits that exosomes may possess.

- **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 is 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 a hospital admission for Acute Decompensated Heart Failure, or ADHF. Cenderitide was designed by scientists at the Mayo Clinic to be the only dual natriuretic peptide receptor agonist. In October 2014, the Company announced that it had entered into an Investigator-Initiated Research Support Agreement with Insulet Corporation. Pursuant to the Agreement, Insulet will support Capricor's research by engaging in certain product development, project management and design control activities in addition to product supply for the planned clinical trial. Capricor intends to utilize the Insulet drug delivery system based on the OmniPod® insulin management system. Capricor is planning to commence a Phase I clinical trial in the first half of 2015.

- **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.

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 patient 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 patent expenses, 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 condensed 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 September 30, 2014 and 2013 were approximately $0.8 million and $0.6 million, respectively. The increase in G&A expenses in the third quarter of 2014 of approximately $0.2 million as compared to the same period of 2013 is primarily attributable to professional fees related to legal, recruiting and increased headcount, as well as additional expenses related to relevant public company compliance.

G&A expenses for the nine months ended September 30, 2014 and 2013 were approximately $2.3 million and $1.5 million, respectively. The increase of approximately $0.8 million in G&A expenses in the nine month period ended September 30, 2014 as compared to the same period of 2013 is primarily attributable to an increase of approximately $0.6 million in professional fees related to legal and recruiting, as well as additional expenses related to relevant public company compliance. Additionally, there was an increase of approximately $0.2 million in G&A expenses related to increased headcount and stock-based compensation expense.

Research and Development Expenses. R&D expenses for the three months ended September 30, 2014 and 2013 were approximately $2.0 million and $1.0 million, respectively. The increase in R&D expenses of approximately $1.0 million in the third quarter of 2014 as compared to the same period of 2013 is primarily due to the timing of clinical development activities, which includes the manufacturing of CAP-1002 for our Phase I/II ALLSTAR trial and our planned DYNAMIC trial. In the three months ended September 30, 2014, the clinical development of CAP-1002 resulted in an increase of approximately $0.7 million in clinical costs primarily related to patient costs, manufacturing costs, site costs and expenses for the operational team that supports the clinical trials. Additionally, there was an increase of approximately $0.2 million in R&D expenses related to our collaboration work with Janssen. Furthermore, there was an increase of approximately $0.1 million related to increased headcount in the R&D department.

R&D expenses for the nine months ended September 30, 2014 and 2013 were approximately $5.2 million and $3.5 million, respectively. The increase in R&D expenses in the nine months ended September 30, 2014 of approximately $1.7 million as compared to the same period of 2013 is primarily due to the timing of clinical development activities, which includes the manufacturing of CAP-1002 for our Phase I/II ALLSTAR trial and our planned DYNAMIC trial. In the nine months ended September 30, 2014, the clinical development of CAP-1002 resulted in an increase of approximately $0.9 million in clinical costs primarily related to patient costs, manufacturing costs, site costs and expenses for the operational team that supports the clinical trials. Additionally, there was an increase of approximately $0.4 million in R&D expenses related to our collaboration work with Janssen. Furthermore, there was an increase of approximately $0.2 million related primarily to increased headcount in the R&D department.

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 $7.0 to $9.5 million during 2014 on the development of CAP-1002, which is primarily related to our Phase II ALLSTAR trial. The Phase I portion of the 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 is administered to patients via intracoronary infusion within 30 days to one year following a heart attack. Phase II is substantially funded 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. If Janssen exercises its exclusive option under the Collaboration Agreement and Exclusive License Option, or the Janssen Agreement, Janssen will thereafter be responsible for any additional trials and future development costs with respect to CAP-1002.

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 8 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 trial involving CAP-1002 and its ability to obtain significant capital to conduct further studies to further develop CAP-1001.

CSps – This product candidate is 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.

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.

Cenderitide – The Company acquired the rights to cenderitide in 2006, and incurred substantial losses surrounding the development of the product. 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 plans to pursue further clinical development of cenderitide in the "post-acute" period following a hospital admission for Acute Decompensated Heart Failure. We expect to spend approximately $0.4 million during 2014 in development expenses in preparation for the planned clinical trial in 2015.

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.

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 drug 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, clinical development and 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 drug candidates; and
- the costs, requirements and timing of, and the ability to secure, regulatory approvals.

Grant Income. Grant income for the three months ended September 30, 2014 and 2013 was approximately $0.3 million and $0.1 million, respectively. This increase in grant income in the third quarter of 2014 as compared to the third quarter of 2013 is primarily related to the Bridge grant awarded by the NIH for the planned DYNAMIC clinical trial, which began incurring expenditures in the third quarter of 2014.

Grant income for the nine months ended September 30, 2014 and 2013 was approximately $0.3 million and $0.5 million, respectively. This decrease in grant income in the first nine months of 2014 as compared to the first nine months of 2013 is primarily due to Capricor's previously awarded grants, which were active in early 2013 through late 2013, at which time the grants reached the end of their respective project periods. Conversely, the only grant in 2014, the Bridge grant, began incurring expenditures in the third quarter of 2014.

Collaboration Income. As a result of the Janssen Agreement, collaboration income for the three months ended September 30, 2014 and 2013 was approximately $1.0 million and $0, respectively. The increase in collaboration income in the three months ended September 30, 2014 as compared to the same period in 2013 is due to the fact that the Janssen Agreement was entered into with Janssen in late 2013, and a payment of $12.5 million was received by Capricor pursuant to the terms of the Janssen Agreement during the first quarter of 2014. A ratable portion of the payment to Capricor was recognized during the three months ended September 30, 2014.

Collaboration income for the nine months ended September 30, 2014 and 2013 was approximately $3.1 million and $0, respectively. The increase in collaboration income in the nine months ended September 30, 2014 over the same period in 2013 is due to the fact that the Janssen Agreement was entered into with Janssen in late 2013, and a payment of $12.5 million was received by Capricor pursuant to the terms of the Janssen Agreement during the first quarter of 2014. A ratable portion of the payment to Capricor was recognized during the nine months ended September 30, 2014.

Investment Income (Loss). Investment income (loss) for the three months ended September 30, 2014 and 2013 was $1,210 and $(27,822), respectively. This increase in investment income in the third quarter of 2014 as compared to the same period in 2013 is primarily due to the timing of sales of marketable securities and interest received in the respective periods.

Investment income for the nine months ended September 30, 2014 and 2013 was $3,129 and $(12,205), respectively. This increase in investment income in the first nine months of 2014 as compared to the same period in 2013 is primarily due to the timing of sales of marketable securities and interest received in the respective periods.

Interest Expense. Interest expense for the three months ended September 30, 2014 and 2013 was $60,091 and $23,353, respectively. This increase in interest expense in the third quarter of 2014 as compared to the same period in 2013 is due to the interest on the CIRM loan award, related to the principal balance being higher in the third quarter of 2014, as compared to the same period of 2013.

Interest expense for the nine months ended September 30, 2014 and 2013 was $140,122 and $33,275, respectively. This increase in interest expense in the first nine months of 2014 as compared to the same period in 2013 is due to the interest on the CIRM loan award as the principal balance outstanding under the loan is higher in the nine months of 2014 as compared to the same period of 2013.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of September 30, 2014 and December 31, 2013 and our net increase (decrease) in cash and cash equivalents for the nine months ended September 30, 2014 and 2013, and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

Liquidity and capital resources	September 30, 2014	December 31, 2013
Cash and cash equivalents	$ 9,805	$ 1,730
Working capital	$ 8,004	$ 1,628
Stockholders' equity (deficit)	$ (4,472)	$ (535)

	Nine months ended September 30,	
Cash flow data	2014	2013
Cash provided by (used in):		
Operating activities	$3,105	$(6,324)

Investing activities	(234)	2,503
Financing activities	5,205	3,927
Net increase in cash and cash equivalents	$8,076	$106

Our total cash resources, not including restricted cash, as of September 30, 2014 were approximately $9.8 million compared to approximately $1.7 million as of December 31, 2013. Total marketable securities, consisting primarily of United States treasuries, were approximately $0.3 million as of each of September 30, 2014 and December 31, 2013. As of September 30, 2014, we had approximately $20.8 million in total liabilities, of which approximately $9.4 million was recorded as deferred income under the Janssen Agreement, and approximately $8.0 million in net working capital. We incurred a net loss of approximately $1.5 million for the three months ended September 30, 2014.

Cash provided by operating activities was approximately $3.1 million for the nine months ended September 30, 2014 and cash used in operating activities was approximately $6.3 million for the nine months ended September 30, 2013. The difference of approximately $9.4 million in cash provided by operating activities for the nine months ended September 30, 2014 as compared to the same period of 2013 is primarily due to our receipt of the $12.5 million payment under the terms of the Janssen Agreement. The increase in cash provided by operating activities was partially offset by an increase in total operating expenses for the nine months ended September 30, 2014 of approximately $2.5 million as compared to the same period of 2013. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, we expect to continue incurring substantial and increasing losses, which will generate negative net cash flows from operating activities, as we expand our technology portfolio and engage in further research and development activities, and, in particular, conduct pre-clinical studies and clinical trials.

Cash used in investing activities was approximately $0.2 million for the nine months ended September 30, 2014 and cash provided by financing activities was approximately $2.5 million for the nine months ended September 30, 2013. The difference in cash used in investing activities for the nine months ended September 30, 2014 as compared to the same period of 2013 is primarily due to the proceeds from sales and maturities of marketable securities.

We had cash flow provided by financing activities of approximately $5.2 million and $3.9 million for the nine months ended September 30, 2014 and 2013, respectively. The difference in cash provided by financing activities for the nine months ended September 30, 2014 as compared to the same period of 2013 is primarily a result of Capricor's CIRM loan disbursements throughout 2014.

Phase II of Capricor's ALLSTAR trial has been funded in large part through a loan award from CIRM. 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, 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. Capricor is planning to commence a Phase I trial of cenderitide in the first half of 2015. Depending on the outcome of the Phase I trial and the availability of resources, it may be followed by a Phase Ib trial and/or Phase II trial. In March 2011, the FDA granted fast track designation to cenderitide. 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 the development of our exosomes program and conduct additional studies with CAP-1002, such as the planned DYNAMIC study and the potential study of CAP-1002 to treat DMD.

From inception through September 30, 2014, Capricor has financed its operations through private sales of its equity securities, NIH grants, a payment from Janssen, and a CIRM loan award. Prior to the merger between Capricor and Nile, Nile financed its operations through public sales of its equity securities. 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

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.

April 2012 Financing. On March 30, 2012, we entered into subscription agreements with certain purchasers pursuant to which we agreed to sell an aggregate of 67,000 shares of our common stock to such purchasers for a purchase price of $20.00 per share (calculated using the post-reverse stock split factor of 1:50). In addition, for each share purchased, each purchaser also received three-fourths of a five-year warrant to purchase an additional share of our common stock at an exercise price of $25.00 per share (calculated using the post-reverse stock split factor of 1:50), resulting in the issuance of warrants to purchase an aggregate of 50,250 shares of our common stock. The total gross proceeds from the offering were $1.3 million, before deducting anticipated selling commissions and expenses of approximately $0.2

million. The closing of the offering occurred on April 4, 2012. In connection with the offering, we engaged Roth Capital Partners, LLC, or Roth, to serve as placement agent. Pursuant to the terms of the placement agent agreement, we agreed to pay Roth a cash fee equal to 7% of the gross proceeds received by us, or approximately $93,800, plus a non-accountable expense allowance of $35,000. Richard B. Brewer, our former Executive Chairman, Joshua A. Kazam, our former President and Chief Executive Officer and a current director of the Company, Daron Evans, our former Chief Financial Officer, and Hsiao Lieu, M.D., our former Executive VP of Clinical Development, participated in the offering on the same terms as the unaffiliated purchasers, and collectively purchased 5,500 shares of our common stock and warrants to purchase 4,125 shares of our common stock for an aggregate purchase price of $110,000.

The offer and sale of the shares and warrants were made pursuant to our shelf registration statement on Form S-3 (SEC File No. 333-165167), which became effective on March 12, 2010. Pursuant to the subscription agreements that we entered into with the purchasers in the April 2012 financing, we agreed to file, within 15 business days after the closing of the offering, a registration statement covering the issuance of the shares of our common stock upon exercise of the warrants and the subsequent resale of such shares, or the Additional Registration Statement, and to cause such registration statement to be declared effective within 90 days following the closing of the offering. In the event the Additional Registration Statement was not declared effective by the SEC within such 90-day period, we agreed to pay liquidated damages to each purchaser in the amount of 1% of such purchaser's aggregate investment amount for each 30-day period until the Additional Registration Statement was declared effective, subject to an aggregate limit of 12% of such purchaser's aggregate investment amount. The Additional Registration Statement (SEC File No. 333-180928) was filed on April 25, 2012 and was declared effective by the SEC on May 7, 2012.

At the consummation of the merger between Capricor and Nile, warrants to purchase 50,063 shares of our common stock, which were issued in the April 2012 financing described above, were exchanged for 50,063 shares of our common stock, and certain April 2012 warrants were cancelled. After the exchange, warrants to purchase 187 shares of our common stock remain outstanding from the April 2012 issuance, which such warrants provide for a strike price of $2.27.

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. 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 intends to refund 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 will 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.

Convertible Preferred Stock. Prior to the merger between Capricor and Nile and without giving effect to the applicable multiplier, Capricor was authorized to issue 5,426,844 shares of convertible preferred stock, which were allocated as follows: Series A-1: 940,000 shares, all of which were issued; Series A-2: 736,844 shares, all of which were issued; and Series A-3: 3,750,000 shares, of which 1,500,000 shares were issued. During 2011 and 2012, the 1,500,000 shares of Series A-3 convertible preferred stock, par value $0.001 per share, were issued by Capricor for cash proceeds of $6,000,000. Immediately prior to the effective time of the merger between Capricor and Nile, all

shares of Capricor preferred stock were converted into shares of Capricor common stock pursuant to the terms of the merger agreement. The shares of Capricor preferred stock that were converted into Capricor common stock as a result of the merger between Capricor and Nile and in accordance with the terms of the merger agreement were exchanged according to the applicable multiplier for 6,591,494 shares of Capricor Therapeutics common stock.

Grant and Sub-grant Award. In 2010, Capricor was awarded $2,993,268 in a federal grant from the NIH to support the project entitled “Safety and Efficacy of Allogeneic Cardiosphere-derived Stem Cells After MI.” The award was issued under the American Recovery and Reinvestment Act of 2009. The award is subject to certain quarterly and annual reporting requirements as well as a final progress report. The award was used to fund a portion of the Phase I clinical trial for the CAP-1002 product candidate, as well as various development activities associated with CAP-1002, and includes, among other permitted costs, certain allowable expenses such as personnel, supplies and certain patient costs. In the second quarter of 2013, the project period of the grant was extended until September 30, 2013 through an approved no-cost extension. The full amount of the award has been disbursed to Capricor.

In 2009, Capricor was awarded $124,791 in a federal grant through the NIH Small Business Innovation Research, or SBIR, program for the project entitled “Characterization and Potency of Optimized Cardiosphere-derived Stem Cell Method” (Phase I). The grant award, which has been completed, was subject to quarterly and annual reporting requirements as stipulated in the Notice of Award, and to certain terms and conditions.

In 2011, Capricor was awarded an additional $397,217 (Phase II) in connection with the SBIR award from the NIH. In 2012, Capricor was awarded a third year under the award and was approved for an additional $425,410 (Phase III). In the third quarter of 2013, the project period of the grant was extended until August 30, 2013 through an approved no-cost extension. The award was complete as of December 31, 2013.

On August 21, 2013, Capricor was approved for a Phase IIB Bridge grant through the NIH 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 Capricor over a period of three years, subject to annual and quarterly reporting requirements. As of September 30, 2014, $259,800 had been incurred under the terms of the award. In June 2014, Capricor received approval from the NIH to deploy this grant to fund the Phase I portion of the DYNAMIC trial. Capricor has been authorized by the FDA to begin clinical investigations for the DYNAMIC clinical trial. The Company intends that the Phase I portion of the DYNAMIC trial will use CAP-1002 to treat patients with advanced heart failure.

Off -Balance Sheet Arrangements

There were no off-balance sheet arrangements as described by Item 303(a)(4) of Regulation S-K as of September 30, 2014.

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 collaborative arrangement 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 patient costs, consulting fees, costs of personnel and supplies for manufacturing, costs of service providers for pre-clinical, clinical 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 patent expenses, 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. In connection with the merger between Capricor and Nile, 50,063 warrants issued in the April 2012 financing were eliminated and 50,063 shares of Company common stock were issued in exchange for cancellation of the warrants to purchase 50,063 shares of Company common stock. Furthermore, 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 September 30, 2014, and no such liability has been reflected on the condensed consolidated balance sheet.

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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.

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.

In June 2014, the FASB issued ASU 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance* ("ASU 2014-10"), which eliminates the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. Additionally, ASU 2014-10 eliminates the separate requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flow and shareholders' equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a

development stage entity that in prior years it had been in the development stage. ASU 2014-10 is effective for fiscal years beginning after December 15, 2014 and interim periods therein, with early adoption permitted. The Company adopted this guidance in the second quarter of fiscal year 2014 on a prospective basis.

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 September 30, 2014, the fair value of our cash, cash equivalents, including restricted cash, and our marketable securities was approximately $13.8 million. Additionally, as of September 30, 2014, Capricor's portfolio consisted of marketable securities, including primarily United States treasuries and 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 only 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 September 30, 2014 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.

We have marked with an asterisk (*) those risk factors below that reflect material changes from the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission on March 31, 2014.

Investment in our common stock involves significant risk. You should carefully consider the information described in the following risk factors, together with the other information appearing elsewhere in this Quarterly Report on Form 10-Q, before making an investment decision regarding our common stock. If any of the events or circumstances described in these risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or a part of your investment in our common stock. Moreover, the risks described below are not the only ones that we face.

Risks Relating to Our Business

**** We need substantial additional funding before we can complete the development of our product candidates. If we are unable to obtain such additional capital, we will be forced to delay, reduce or eliminate our product development programs and may not have the capital required to otherwise operate our business.***

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials and establishing manufacturing capabilities, is expensive. As of September 30, 2014, we had cash, cash resources, and marketable securities totaling approximately $10.1 million, plus approximately $3.7 million restricted cash in loans for our ALLSTAR clinical trial. We have not generated any product revenues, and will not generate any product revenues until, and only if, we receive approval to sell our drug candidates from the U.S. Food and Drug Administration, or FDA, and other regulatory authorities for our product candidates.

From inception, we have financed our operations through public and private sales of our equity and debt securities, NIH grants, and a CIRM loan award. We also recently entered into a collaboration agreement with Janssen Biotech, Inc., or Janssen, which provides for funding for the collaboration of our cell therapy program for cardiovascular applications, including CAP-1002. As we have not generated any revenue from operations 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 expect our research and development expenses to increase in connection with our ongoing activities, particularly as we continue to develop cenderitide and potentially initiate clinical development of CU-NP. Our research and development expenses will also increase as we further the development of our exosome program and conduct additional studies with CAP-1002, such as the DYNAMIC study and the potential study of DMD. In addition, our expenses could increase beyond expectations if the FDA requires that we perform additional studies beyond those that we currently anticipate, which may also delay the timing of any potential product approval. Other than our cash on hand, we currently have no commitments or arrangements for any additional financing to fund the research and development of cenderitide, CU-NP, exosomes or CAP-1002 for DMD. We have commenced certain development activities in connection with our cenderitide product candidate, and we anticipate commencing a clinical trial in 2015. We are also planning to initiate the DYNAMIC study before the end of 2014.

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 additional 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 forecasts regarding our beliefs of the sufficiency of our financial resources to support our current and planned operations are forward-looking statements and involve significant risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, cost and results of our research and development activities, especially our Phase II clinical trial of CAP-1002, our planned DYNAMIC trial, our planned exosomes and cenderitide programs and our planned development of CAP-1002 as a potential treatment of DMD;
- the continued availability of funding from NIH and CIRM;
- the costs and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the terms and timing of any collaboration, licensing or other arrangements that we may establish;
- the cost and timing of completion of clinical and commercial-scale outsourced manufacturing activities; and
- the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

**** We have a history of net losses, and we expect losses to continue for the foreseeable future. In addition, a number of factors may cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.***

We have a history of net losses, expect to continue to incur substantial and increasing net losses for the foreseeable future, and may never achieve or maintain profitability. Our operations to date have been primarily limited to organizing and staffing our company, developing our technology, and undertaking pre-clinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history. Specifically, our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to -quarter and year-to -year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, as well as other factors described elsewhere in this Quarterly Report on Form 10-Q:

- our need for substantial additional capital to fund our development programs;
- delays in the commencement, enrollment, and timing of clinical testing;
- the success of the ALLSTAR clinical trial through all stages of clinical development;
- the success of clinical trials of cenderitide and CU-NP product candidates through all stages of clinical development, if commenced;

- the success of the planned DYNAMIC clinical trial through all stages of clinical development;
- the viability of exosomes as a potential product candidate and the success of all stages of its pre-clinical and clinical development;
- the viability of CAP-1002 as a potential product candidate for the treatment of DMD and the success of all stages of its pre-clinical and clinical development;
- any delays in regulatory review and approval of our product candidates in clinical development;
- our ability to receive regulatory approval or commercialize our product candidates, within and outside the United States;
- potential side effects of our current or future products and product candidates that could delay or prevent commercialization or cause an approved treatment drug to be taken off the market;
- regulatory difficulties relating to products that have already received regulatory approval;
- market acceptance of our product candidates;
- our ability to establish an effective sales and marketing infrastructure once our products are commercialized;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- competition from existing products or new products that may emerge;
- guidelines and recommendations of therapies published by various organizations;
- the ability of patients to obtain coverage of or sufficient reimbursement for our products;
- our ability to maintain adequate insurance policies;
- our ability to successfully manufacture our product candidates on a timely basis;
- our dependency on third parties to formulate and manufacture our product candidates;
- our ability to maintain our current manufacturing facility and secure other facilities as determined to be necessary;
- costs related to and outcomes of potential intellectual property litigation;
- compliance with obligations under intellectual property licenses with third parties;
- our ability to seek regulatory approvals for our product candidates;

- our ability to implement additional internal systems and infrastructure;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively; and
- the ability of our senior management who have limited experience in managing a public company to manage our business and operations.

**** The Company's technology is not yet proven and each of our product candidates is in an early stage of development.***

Each of the Company's six product candidates, CAP-1002, CAP-1001, cardiospheres, exosomes, cenderitide and CU-NP, is in an early stage of development and requires extensive clinical testing before it may be approved by the FDA, or another regulatory authority in a jurisdiction outside the United States, which could take several years to complete, if ever. The effectiveness of the Company's technology has not been definitively proven in completed human clinical trials or preclinical studies. The Company's failure to establish the efficacy of its technology would have a material adverse effect on the Company. We cannot predict with any certainty the results of such clinical testing, including the results of our ALLSTAR trial or the planned DYNAMIC trial. We cannot predict with any certainty if, or when, we might commence any clinical trials of our product candidates other than the ALLSTAR trial and the DYNAMIC trial or whether such trials will yield sufficient data to permit us to proceed with additional clinical development and ultimately submit an application for regulatory approval of our product candidates in the United States or abroad, or whether such applications will be accepted by the appropriate regulatory agency.

We may not be able to manage our growth.

Should we achieve our near-term milestones, of which no assurance can be given, our long-term viability will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

Risks Relating to Clinical and Commercialization Activities

Our product candidates will require substantial time and resources in order to be developed, and there is no guarantee that we will develop them successfully.

We have not completed the development of any products and may not have products to sell commercially for many years, if at all. Our potential products will require substantial additional research and development time and expense, as well as extensive clinical trials and perhaps additional preclinical testing, prior to commercialization, which may never occur. There can be no assurance that products will be developed successfully, perform in the manner anticipated, or be commercially viable.

Our success depends upon the viability of our product candidates and we cannot be certain any of them will receive regulatory approval to be commercialized.

We will need FDA approval to market and sell any of our product candidates in the United States and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any of our product candidates, we must submit to the FDA a new drug application, or NDA, or a biologics license application, or BLA, demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as pre-clinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity, and novelty of the product candidate, and requires substantial resources for research, development, and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation, administrative action or changes in FDA policy that occur prior to or during our regulatory review.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs or BLAs, as applicable. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. Failure to obtain FDA approval of any of our product candidates will reduce our number of salable products and, therefore, corresponding product revenues, and will have a material and adverse impact on our business.

**** The Company has limited experience in conducting clinical trials.***

The Company has limited human clinical trial experience with respect to its product candidates. The clinical testing process is governed by stringent regulation and is highly complex, costly, time-consuming, and uncertain as to outcome (and pharmaceutical products and products used in the regeneration of tissue may invite particularly close scrutiny and requirements from the FDA and other regulatory bodies). Our failure or the failure of our collaborators to conduct human clinical trials successfully or our failure to capitalize on the results of human clinical trials for our product candidates would have a material adverse effect on the Company. If our clinical trials of our product candidates or future product candidates do not sufficiently enroll or produce results necessary to support regulatory approval in the United States or elsewhere, or if they show undesirable side effects, we will be unable to commercialize these product candidates.

To receive regulatory approval for the commercial sale of our product candidates, we must conduct adequate and well-controlled clinical trials to demonstrate efficacy and safety in humans. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. In addition, the results of our clinical trials may show that our product candidates are ineffective or may cause undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in the denial of regulatory approval by the FDA and other regulatory authorities. In addition, negative or inconclusive results may result in:

·the withdrawal of clinical trial participants;

·the termination of clinical trial sites or entire trial programs;

·costs of related litigation;

·substantial monetary awards to patients or other claimants;

·impairment of our business reputation;
·loss of revenues; and
·the inability to commercialize our product candidates.

**** Delays in the commencement, enrollment, and completion of clinical testing could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.***

Delays in the commencement, enrollment or completion of clinical testing could significantly affect our product development costs. A clinical trial may be suspended or terminated by the Company, the FDA, or other regulatory authorities due to a number of factors. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for

the same indication as our product candidates, may be required to withdraw from a clinical trial as a result of changing standards of care, or may become ineligible to participate in clinical studies. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement, enrollment and completion of clinical trials can be delayed for a number of reasons, including, but not limited to, delays related to:

- findings in preclinical studies;
- reaching agreements on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining regulatory approval to commence a clinical trial;
- complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial, or being required to conduct additional trials before moving on to the next phase of trials;
- obtaining institutional review board, or IRB, approval to conduct a clinical trial at numerous prospective sites;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including size of patient population, nature of trial protocol, meeting the enrollment criteria for our studies, screening failures, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues, or side effects from the therapy, or who are lost to further follow-up;
- manufacturing sufficient quantities of a product candidate for use in clinical trials on a timely basis;
- complying with design protocols of any applicable special protocol assessment we receive from the FDA;
- severe or unexpected drug-related side effects experienced by patients in a clinical trial;
- collecting, analyzing and reporting final data from the clinical trials;
- breaches in quality of manufacturing runs that compromise all or some of the doses made, positive results in FDA-required viral testing; karyotypic abnormalities in our cell product, or contamination in our manufacturing facilities, all of which events would necessitate disposal of all cells made from that source;
- availability of materials provided by 3rd parties necessary to manufacture our product candidates;
- availability of adequate amounts of acceptable tissue for preparation of master cell banks for our products;

- our inability to find a tissue source with an HLA haplotype that is compatible with the recipient may lead to limited utility of the product in a broad population; and

- requirements to conduct additional trials and studies, and increased expenses associated with the services of the Company's CROs and other third parties.

In addition, a clinical trial may be suspended or terminated by us, the FDA, or other regulatory authorities due to a number of factors. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, we or our development partners, if any, may be delayed in obtaining, or may not be able to obtain, marketing approval for these product candidates. We may not be able to obtain approval for indications that are as broad as intended, or we may be able to obtain approval only for indications that are entirely different than those indications for which we sought approval.

Changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit our clinical trial protocols to institutional review boards, or IRBs, for re-examination, which may impact the costs, timing, or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same or similar indications may have been introduced to the market and established a competitive advantage. Any delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; or
- diminish any competitive advantages that we may otherwise enjoy.

As the results of earlier clinical trials are not necessarily predictive of future results, any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Even if our clinical trials are completed as planned, including our ALLSTAR clinical trial of CAP-1002, we cannot be certain that their results will support the claims of our product candidates. Positive results in pre-clinical testing and early clinical trials do not ensure that results from later clinical trials will also be positive, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase III clinical trials, even after seeing promising results in earlier clinical trials.

Our clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs and/or BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials to date involve small patient populations. Because of the small sample size, the results of these clinical trials may not be indicative of future results.

Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase II, Phase III or other clinical programs we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates.

Our products face a risk of failure due to adverse immunological reactions.

A potential risk of an allogeneic therapy such as that being tested by the Company is that patients might develop an immune response to the cells being infused. Such an immune response may induce adverse clinical effects which would impact the safety of the Company's products and the success of our trials. Additionally, if research subjects have pre-existing antibodies or other immune sensitization to our cells, there is a potentiality that our cells and the therapy would be rendered ineffective.

* ***Our business faces significant government regulation, and there is no guarantee that our product candidates will receive regulatory approval.***

Our research and development activities, preclinical studies, anticipated human clinical trials, and anticipated manufacturing and marketing of our potential products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, as well as by regulatory authorities in other countries. In the United States, our product candidates are subject to regulation as biological products under the Public Health Service Act or as combination biological products/medical devices. Different regulatory requirements may apply to our products depending on how they are categorized by the FDA under these laws. These regulations can be subject to substantial and significant interpretation, addition, amendment or revision by the FDA and by the legislative process. The FDA may determine that we will need to undertake clinical trials beyond those currently planned. Furthermore, the FDA may determine that results of clinical trials do not support approval for the product. Similar determinations may be encountered in foreign countries. The FDA will continue to monitor products in the market after approval, if any, and may determine to withdraw its approval or otherwise seriously affect the marketing efforts for any such product. The same possibilities exist for trials to be conducted outside of the United States that are subject to regulations established by local authorities and local law. Any such determinations would delay or deny the introduction of our product candidates to the market and have a material adverse effect on our business, financial condition, and results of operations.

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Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with Good Manufacturing Practices or GMPs and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards. Other risks include:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication, or field alerts to physicians and pharmacies;
- regulatory authorities may withdraw their approval of the product or require us to take our approved products off the market;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of our products;
- we may have limitations on how we promote our products; and
- we may be subject to litigation or product liability claims.

Even if our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our product candidates outside of the United States. In order to market and commercialize any product candidate outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. For example, European regulatory authorities generally require a trial comparing the efficacy of the new drug to an existing drug prior to granting approval. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. Such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales and potential royalties, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties.

Even if United States regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies. Given the number of recent high-profile adverse safety events with certain drug products, the FDA may require, as a condition of

approval, costly risk management programs which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, and restrictions on direct-to-consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA's drug approval process and the agency's efforts to assure the safety of marketed drugs has resulted in the proposal of new legislation addressing drug safety issues. If enacted, any new legislation could result in delays or increased costs during the period of product development, clinical trials, and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements. Any of these restrictions or requirements could force us to conduct costly studies or increase the time for us to become profitable. For example, any labeling approved for any of our product candidates may include a restriction on the term of its use, or it may not include one or more of our intended indications.

Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping, and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers, and manufacturers' facilities are subject to continuous review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, such as current Good Manufacturing Practices or GMPs, a regulatory agency may:

- issue warning letters;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions, and penalties for noncompliance;
- impose other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

* ***We have limited manufacturing capability, and may not be able to maintain our manufacturing licenses.***

We presently maintain our laboratories and research facilities in leased premises at CSMC. We presently manufacture our cells in an accredited GMP facility which is owned by and located within CSMC. Our intention is to manufacture cells at this facility for our ALLSTAR Phase II trial, our planned DYNAMIC trial, and for any clinical work involving CAP-1002 as a potential treatment for DMD. We also intend to utilize our premises at CSMC to develop and manufacture exosomes. If the lease is terminated or if CSMC revokes its permission to allow us to utilize the GMP facility, we would have to secure alternative facilities in which to operate our research and development activities and/or manufacture our products, which would involve a significant monetary investment and would negatively impact the progress of our clinical trials and regulatory approvals. In addition, we may have to build out our own manufacturing facility for any Phase III trial or establish a collaboration agreement with a third party.

We are required to obtain and maintain certain licenses in connection with our manufacturing facilities and activities. We have been issued a Manufacturing License and a Tissue Bank License from the State of California. There is no guarantee that any licenses issued to us will not be revoked or forfeited by operation of law or otherwise. If we were denied any required license or if any of our licenses were to be revoked or forfeited, we would suffer significant harm. Additionally, if a serious adverse event in any of our clinical trials was to occur during the period in which any required license was not in place, we could be exposed to additional liability if it were determined that the event was due to our fault and we had not secured the required license.

We obtain the donor hearts from which our CDCs are manufactured from organ procurement organizations, or OPOs. There is no guarantee that the OPOs which currently provide donor hearts to us will be able to continue to supply us with donor hearts in the future or that an alternative OPO will be available to us. If those OPOs or an alternative OPO is not able or willing to supply us with donor hearts, we would be unable to produce our CDCs and the development of our lead product candidate would be significantly impaired and possibly terminated. Additionally, OPOs are subject to regulations of various government agencies. There is no guarantee that laws and regulations pursuant to which our OPOs provide donor hearts will not change making it more difficult or even impossible for the OPOs to continue to supply us with the hearts we need to produce our product.

* ***We have no prior experience in manufacturing product for large clinical trials or commercial use.***

Our manufacturing experience has been limited to manufacturing CAP-1002 for the current ALLSTAR trial. We have no prior history or experience in manufacturing our allogeneic product or any other product for any clinical use and no experience manufacturing any product for large clinical trials or commercial use. Our product candidates have not previously been tested in any large trials to show safety or efficacy, nor are they available for commercial use. We face risks of manufacturing failures and risks of making products that are not proven to be safe or effective.

**** As we continue with the development of Cenderitide or CU-NP, we will rely exclusively on third parties to formulate and manufacture these product candidates and provide us with the devices necessary to administer Cenderitide or CU-NP.***

We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities for the production of Cenderitide or CU-NP. We lack the resources and expertise to formulate or manufacture our own product candidates. As we continue with the development of Cenderitide or CU-NP, we will have to contract with one or more manufacturers to manufacture, supply, store, and distribute drug supplies for our clinical trials. If either of these product candidates receives FDA approval, we will rely on one or more third-party contractors to manufacture supplies of our drug candidates. In addition, these product candidates may require the use of one or more medical devices for infusion into patients. We will have to contract with one or more device manufacturers to manufacture and supply the devices to be used in the dosing procedures. Our current and anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers needed to manufacture our product candidates or the necessary devices on acceptable terms or at all, because the number of potential manufacturers is limited, and subsequent to approval of an NDA or BLA, the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer may have to be educated in, or develop substantially equivalent processes for, production of our products or the devices after receipt of FDA approval, if any.

- Some of the raw materials needed to manufacture our product candidates are available from a very limited number of suppliers. Although we believe we have good relationships with these suppliers, we may have difficulty identifying alternative suppliers if our arrangements with our current suppliers are disrupted or terminated.

- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any.

- Our third-party manufacturers might be unable to manufacture or supply us with sufficient quantities of devices or acceptable materials necessary for the development or use of our product candidates.

- Our product candidates may not perform well, or if at all, with the devices received from third-party manufacturers.

- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products or the materials or devices needed to manufacture or utilize our product candidates.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA, or the commercialization of our product candidates, or result in higher costs or deprive us of potential product revenues.

Risks Related to Our Intellectual Property

We may face uncertainty and difficulty in obtaining and enforcing our patents and other proprietary rights.

Our success will depend in large part on our ability to obtain, maintain, and defend patents on our products, obtain licenses to use third party technologies, protect our trade secrets and operate without infringing the proprietary rights of others. Legal standards regarding the scope of claims and validity of biotechnology patents are uncertain and evolving. There can be no assurance that our pending, licensed-in or owned patent applications will be approved, or that challenges will not be instituted against the validity or enforceability of any patent licensed-in or owned by us. Additionally, we have entered into various confidentiality agreements with employees and third parties. There is no assurance that such agreements will be honored by such parties or enforced in whole or part by the courts. The cost of litigation to uphold the validity and prevent infringement of a patent is substantial. Furthermore, there can be no assurance that others will not independently develop substantially equivalent technologies not covered by patents to which we own rights or obtain access to our know-how. In addition, the laws of certain countries may not adequately protect our intellectual property. Our competitors may possess or obtain patents on products or processes that are necessary or useful to the development, use, or manufacture of our products. There can also be no assurance that our proposed technology will not infringe patents or proprietary rights owned by others, with the result that others may bring infringement claims against us and require us to license such proprietary rights, which may not be available on commercially reasonable terms, if at all. Any such litigation, if instituted, will have a material adverse effect, including monetary penalties, diversion of management resources, and injunction against continued manufacture, use, or sale of certain products or processes.

Some of our technology has resulted, and will result, from research funded by agencies of the United States government and the State of California. As a result of such funding, the United States government and the State of California have certain rights in the technology developed with the funding. These rights include a non-exclusive, paid-up, worldwide license under such inventions for any governmental purpose. In addition, under certain conditions, the government has the right to require us to grant third parties licenses to such technology. The licenses by which we have obtained some of our intellectual property are subject to the rights of the funding agencies. We also rely upon non-patented proprietary know-how. There can be no assurance that we can adequately protect our rights in such non-patented proprietary know-how, or that others will not independently develop substantially equivalent proprietary information or techniques or gain access to our proprietary know-how. Any of the foregoing events could have a material adverse effect on us. In addition, if any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the U.S. transitioned in March 2013 to a “first to file” system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO and may become involved in opposition, derivation, reexamination, inter-parties review or interference proceedings challenging our patent rights or the patent rights of our licensors. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our or our licensors’ patent rights, which could adversely affect our competitive position.

The USPTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not become effective until March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents and those licensed to us.

* ***It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If we fail to protect or enforce our intellectual property rights adequately or secure rights to patents of others, the value of our intellectual property rights would diminish.***

Our commercial viability will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell, or importing our products is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We have licensed certain patent and other intellectual property rights that cover our CAP-1002, CAP-1001, and CSps product candidates from University of Rome, JHU and CSMC. We have also licensed certain patent and other intellectual property rights that cover exosomes from CSMC. Under the license agreements with University of Rome and JHU, those institutions prosecute and maintain their patents and patent applications in collaboration with us. We rely on these institutions to file, prosecute, and maintain patent applications, and otherwise protect the intellectual property to which we have a license, and we have not had and do not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. We cannot be certain that such activities by these institutions have been or will be conducted in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. Under the Amended CSMC License Agreement and the Exosomes License Agreement, we have assumed, in coordination with CSMC, responsibility for the prosecution and maintenance of all patents and patent applications. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would also be subject to the cooperation of the third parties.

We license certain patent and other intellectual property rights that cover our cenderitide and CU-NP product candidates from Mayo. In the past, we have relied on Mayo to file, prosecute, and maintain patent applications, and otherwise protect the intellectual property to which we have a license, and, prior to the Amended Mayo License Agreement, we did not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. We cannot be certain that the activities conducted by Mayo have been or will be conducted in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. With the execution of the Amended Mayo License Agreement, we are responsible for the prosecution and maintenance of the Mayo patents and patent applications covered by our license, and the associated costs and expenses. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would be subject to the cooperation of the third parties.

In October 2014, we entered into a Transfer Agreement with Medtronic, Inc. or Medtronic, pursuant to which we received an assignment of patent rights that were owned or co-owned by Medtronic relating to natriuretic peptides. We have responsibility for the prosecution and maintenance of such patents and patent applications at our expense. We cannot be certain that the activities conducted by Medtronic prior to our acquisition of these patents and patent rights were conducted in compliance with applicable law and regulations, or will result in valid and enforceable

patents. Our enforcement of certain of these assigned patents or defense of any claims asserting the invalidity of these patents would be subject to the cooperation of third parties.

The patent positions of pharmaceutical and biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biopharmaceutical patents has emerged to date in the United States. The biopharmaceutical patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license or third-party patents. Further, if any of our patents are deemed invalid and unenforceable, it could impact our ability to commercialize or license our technology.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of any of our patents;
- we might not have been the first to make the inventions covered by any issued patents or patent applications we may have (or third parties from whom we license intellectual property may have);
- we might not have been the first to file patent applications for these inventions;
- it is possible that any pending patent applications we may have will not result in issued patents;
- any issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators, and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how.

If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

Our viability also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, we require all of our employees, consultants, advisors and contractors to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party’s activities do not infringe our rights to these patents. In addition, the United States Supreme Court has recently invalidated some tests used by the United States Patent and Trademark Office, or USPTO, in granting patents over the past 20 years. As a consequence, issued patents may be found to contain invalid claims according to the newly revised standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation in a re-examination proceeding before the USPTO or during litigation under the revised criteria which make it more difficult to obtain patents.

Furthermore, a third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents. We have agreed to indemnify certain of our commercial partners against certain patent infringement claims brought by third parties. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Risks Related to Our Relationships with Third Parties

* ***We are largely dependent on our relationships with our licensors and collaborators and there is no guarantee that such relationships will be maintained or continued.***

We have entered into certain license agreements for certain intellectual property rights which are essential to enable us to develop and commercialize our products. Agreements have been entered into with the University of Rome, JHU and CSMC, which is also a shareholder of ours. Each of those agreements provides for an exclusive license to certain patents and other intellectual property and requires the payment of fees, milestone payments and/or royalties to the institutions that will reduce our net revenues, if and to the extent that we have future revenues. Each of those agreements also contains additional obligations that we are required to satisfy. There is no guarantee that we will be able to satisfy all of our obligations under our license agreements to each of the institutions and that such license agreements will not be terminated. Each of the institutions receives funding from independent sources such as the NIH and other private not-for-profit sources and are investigating scientific and clinical questions of interest to their own principal investigators as well as the scientific and clinical communities at large. These investigators (including Capricor's founder, Dr. Eduardo Marbán, who is the Director of the Heart Institute at CSMC) are under no obligation to conduct, continue, or conclude either current or future studies utilizing our stem cell or exosomes technology, and they are not compelled to license any further technologies or intellectual property rights to us except as may be stated in the applicable licensing agreements between those institutions and us. Changes in these collaborators' research interests or their funding sources away from our technology would have a material adverse effect on us. We are substantially dependent on our relationships with these institutions from which we license the rights to our technologies and know-how. If requirements under our license agreements are not met, we could suffer significant harm, including losing rights to our product candidates.

Our rights to our cenderitide and CU-NP drug candidates were both derived from separate license agreements between us and Mayo. On November 14, 2013, we entered into an Amended and Restated Exclusive License Agreement, which we refer to as the Amended Mayo Agreement, with Mayo pursuant to which the rights to both cenderitide and CU-NP were included in the Amended Mayo Agreement and many of the terms of the former agreements were revised on terms more favorable to us. We are substantially dependent on our relationship with Mayo with respect to the rights to these two drug candidates. If requirements under our license agreement are not met, we could suffer significant harm. In order to develop these products, we will need to maintain the intellectual property rights to these product candidates. The Amended Mayo Agreement requires us to perform certain obligations that affect our rights under the Amended Mayo Agreement, including making cash payments if we were to enter into certain types of business transactions. If we fail to comply with our obligations required under the Amended Mayo Agreement, we could lose important patent and other intellectual property rights which may be critical to our business.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology.

Finally, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our product candidates and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

* ***We have received government grants and a loan award which impose certain conditions on our operations.***

Commencing in 2009, we received several grants from the NIH to fund various projects, including Phase I of the ALLSTAR trial. In 2014, we received a grant from the NIH to fund the planned DYNAMIC trial. These awards are subject to annual and quarterly reporting requirements. If we fail to meet these requirements, the NIH could cease further funding.

On February 5, 2013, we entered into a Loan Agreement with CIRM, pursuant to which CIRM has agreed to disburse $19,782,136 to us over a period of approximately three and one-half years to support Phase II of our ALLSTAR clinical trial. Under the Loan Agreement, we are required to repay the CIRM loan with interest at maturity. The loan also provides for the payment of a risk premium whereby we are required to pay CIRM a premium 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 from the original issuance at our option if certain conditions are met. CIRM has the right to cease disbursements if a no-go milestone occurs or certain other conditions are not satisfied. The timing of the distribution of funds pursuant to the Loan Agreement is contingent upon the availability of funds in the California Stem Cell Research and Cures Fund in the State Treasury, as determined by CIRM in its sole discretion. So long as we are not in default, the loan may be forgiven during the term of the project period if we abandon the trial due to the occurrence of a no-go milestone. After the end of the project period, the loan may be forgiven if we elect to abandon the project under certain circumstances. Under the Loan Agreement, we are also required to meet certain financial milestones by demonstrating to CIRM prior to each disbursement of loan proceeds that we have funds available sufficient to fund 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. There is no assurance that we will meet our milestones under the Loan Agreement or that CIRM will not discontinue the disbursement of funds.

If we enter into strategic partnerships, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to terms unfavorable to us.

If we do not establish strategic partnerships, we will have to undertake development and commercialization efforts on our own, which would be costly and adversely impact our ability to commercialize any future products or product candidates. If we enter into any strategic partnerships with pharmaceutical, biotechnology or other life sciences companies, we will be subject to a number of risks, including:

- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of product candidates;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- strategic partners may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products;
- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic partner's business strategy may also adversely affect a strategic partner's willingness or ability to complete its obligations under any arrangement; and
- strategic partners could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

Risks Related to Competitive Factors

Our products will likely face intense competition.

The Company is engaged in fields that are characterized by extensive worldwide research and competition by pharmaceutical companies, medical device companies, specialized biotechnology companies, hospitals, physicians and academic institutions, both in the United States and abroad. We will experience intense competition with respect to our existing and future product candidates. The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies. Many of these organizations competing with us have substantially greater financial resources, larger research and development staffs and facilities, greater clinical trial experience, longer drug development history in obtaining regulatory approvals, and greater manufacturing, distribution, sales and marketing capabilities than we do. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies, and research organizations actively engaged in research and development of products which may target the same indications as our product candidates. We expect any future products and product candidates that we develop to compete on the basis of, among other things, product efficacy and safety, time to market, price, extent of adverse side effects, and convenience of treatment procedures. One or more of our competitors may develop products based upon the principles underlying our proprietary technologies earlier than we do, obtain approvals for such products from the FDA more rapidly than we do, or develop alternative products or therapies that are safer, more effective and/or more cost effective than any product developed by us. Our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, useful, and less costly than ours and may also be more successful than us in manufacturing and marketing their products.

Our future success will depend in part on our ability to maintain a competitive position with respect to evolving therapies as well as other novel technologies. There can be no assurance that existing or future therapies developed by others will not render our potential products obsolete or noncompetitive. The drugs that we are attempting to develop will have to compete with existing therapies. In addition, companies pursuing different but related fields represent substantial competition. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures, or other collaborations.

**** If we are unable to retain and recruit qualified scientists and advisors, or if any of our key executives, key employees or key consultants discontinues his or her employment or consulting relationship with us, it may delay our development efforts or otherwise harm our business. In addition, several of our employees and consultants render services on a part-time basis to us or to other companies.***

All former employees of Nile were terminated upon consummation of the merger between Nile and Capricor. We do not currently have any employees who have experience in the development of natriuretic peptides. The loss of any of our key employees or key consultants could impede the achievement of our research and development objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to the Company's success. The Company may be unable to attract and retain personnel on acceptable terms given the competition among biotechnology, biopharmaceutical, and health care companies, universities, and non-profit research institutions for experienced scientists. Certain of the Company's officers, directors, scientific advisors, and/or consultants or certain of the officers, directors, scientific advisors, and/or consultants hereafter appointed may from time to time serve as officers, directors, scientific advisors, and/or consultants of other biopharmaceutical or biotechnology companies. The Company may not maintain "key man" insurance policies on any of its officers or employees. All of the Company's employees will be employed "at will" and, therefore, each employee may leave the employment of the Company at any time. If we are unable to retain our existing employees, including qualified scientific personnel, and attract additional qualified candidates, the Company's business and results of operations could be adversely affected.

Because of the specialized nature of our technology, we are dependent upon existing key personnel and on our ability to attract and retain qualified executive officers and scientific personnel for research, clinical studies, and development activities conducted or sponsored by us. There is intense competition for qualified personnel in our fields of research and development, and there can be no assurance that we will be able to continue to attract additional qualified personnel necessary for the development and commercialization of our product candidates or retain our current personnel. Dr. Linda Marbán, our Chief Executive Officer and employee, also provides services on a part-time basis to CSMC as do several other of our employees and Dr. Frank Litvack is only a part-time consultant to the Company and provides services to other non-competing enterprises. These individuals' multiple responsibilities on behalf of the Company and other entities could cause the Company harm in that such employees are unable to devote their full time and attention to the Company.

If we do not establish strategic partnerships, we will have to undertake development and commercialization efforts on our own, which would be costly and delay our ability to commercialize any future products or product

candidates.

An element of our business strategy includes potentially partnering with pharmaceutical, biotechnology and other companies to obtain assistance for the development and potential commercialization of our product candidates, including the cash and other resources we need for such development and potentially commercialization. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. If we are unable to negotiate strategic partnerships for our product candidates we may be forced to curtail the development of a particular candidate, reduce or delay its development program, delay its potential commercialization, reduce the scope of our sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, we will bear all the risk related to the development of that product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain substantial additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

We have no experience selling, marketing, or distributing products and no internal capability to do so.

The Company currently has no sales, marketing, or distribution capabilities. We do not anticipate having resources in the foreseeable future to allocate to the sales and marketing of our proposed products. Our future success depends, in part, on our ability to enter into and maintain sales and marketing collaborative relationships, or on our ability to build sales and marketing capabilities internally. If we enter into a sales and marketing collaborative relationship, then we will be dependent upon the collaborator’s strategic interest in the products under development, and such collaborator’s ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources, and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

The commercial viability of our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance among physicians, the medical community, and patients, and coverage and reimbursement of them by third-party payors, including government payors. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- limitations or warnings contained in a product's FDA-approved labeling;
- changes in the standard of care for the targeted indications for any of our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval;
- limitations inherent in the approved indication for any of our product candidates compared to more commonly understood or addressed conditions;
- lower demonstrated clinical safety and efficacy compared to other products;
- prevalence and severity of adverse effects;
- ineffective marketing and distribution efforts;
- lack of availability of reimbursement from managed care plans and other third-party payors;
- lack of cost-effectiveness;
- timing of market introduction and perceived effectiveness of competitive products;
- availability of alternative therapies at similar costs; and
- potential product liability claims.

Our ability to effectively promote and sell our product candidates in the marketplace will also depend on pricing and cost effectiveness, including our ability to manufacture a product at a competitive price. We will also need to demonstrate acceptable evidence of safety and efficacy and may need to demonstrate relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. If our approved drugs fail to achieve market acceptance, we will not be able to generate significant revenue, if any.

Our ability to generate product revenues will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to generate significant sales of our products depends on the availability of adequate coverage and reimbursement from third-party payors. Healthcare providers that purchase medicine or medical products for treatment of their patients generally rely on third-party payors to reimburse all or part of the costs and fees associated with the products. Adequate coverage and reimbursement from governmental, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of our products.

In addition, the market for our future products will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. Industry competition to be included in such formularies results in downward pricing pressures on pharmaceutical companies. Third-party payors may refuse to include a particular branded drug in their formularies when a generic equivalent is available.

All third-party payors, whether governmental or commercial, whether inside the United States or outside, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical technology exists among all these payors. Therefore, coverage of and reimbursement for medical products can differ significantly from payor to payor.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products may not be available or adequate in either the United States or international markets, limiting our ability to sell our products on a profitable basis.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payors, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payors increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover our drugs. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for any of our products, once approved, market acceptance of our products could be reduced.

Risks Related to Product and Environmental Liability

Our products may expose us to potential product liability, and there is no guarantee that we will be able to obtain and maintain adequate insurance to cover these liabilities.

The testing, marketing, and sale of human cell therapeutics, pharmaceuticals, and services entail an inherent risk of adverse effects or medical complications to patients and, as a result, product liability claims may be asserted against us. A future product liability claim or product recall could have a material adverse effect on the Company. There can be no assurance that product liability insurance will be available to us in the future on acceptable terms, if at all, or that coverage will be adequate to protect us against product liability claims. In the event of a successful claim against the Company, insufficient or lack of insurance or indemnification rights could result in liability to us, which could have a material adverse effect on the Company and its future viability. The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval, if at all, expose the Company to the risk of product liability claims. Product liability claims might be brought against the Company by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

·withdrawal of clinical trial participants;

·termination of clinical trial sites or entire trial programs;

·costs of related litigation;

·substantial monetary awards to patients or other claimants;

·decreased demand for our product candidates;

·impairment of our business reputation;

·loss of revenues; and

·the inability to commercialize our product candidates.

The Company has obtained clinical trial insurance coverage for its clinical trials. However, such insurance coverage may not reimburse the Company or may not be sufficient to reimburse it for any expenses or losses it may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect the Company against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against the Company could have a material adverse effect on us and, if judgments exceed our insurance coverage, could decrease our cash position and adversely affect our business.

Our business involves risk associated with handling hazardous and other dangerous materials.

Our research and development activities involve the controlled use of hazardous materials, chemicals, human blood and tissue, animal blood and blood products, and animal tissue, biological waste, and various radioactive compounds. The risk of accidental contamination or injury from these materials cannot be completely eliminated. The failure to comply with current or future regulations could result in the imposition of substantial fines against the Company, suspension of production, alteration of our manufacturing processes, or cessation of operations.

Our business depends on compliance with ever-changing environmental laws.

We cannot accurately predict the outcome or timing of future expenditures that may be required to comply with comprehensive federal, state and local environmental laws and regulations. We must comply with environmental laws that govern, among other things, all emissions, waste water discharge and solid and hazardous waste disposal, and the remediation of contamination associated with generation, handling and disposal activities. To date, the Company has not incurred significant costs and is not aware of any significant liabilities associated with its compliance with federal, state and local laws and regulations. However, environmental laws have changed in recent years and the Company may become subject to stricter environmental standards in the future and may face large capital expenditures to comply with environmental laws. We have limited capital and we are uncertain whether we will be able to pay for significantly large capital expenditures that may be required to comply with new laws. Also, future developments, administrative actions or liabilities relating to environmental matters may have a material adverse effect on our financial condition or results of operations.

Risks Related to Our Common Stock

**** We expect that our stock price will fluctuate significantly, and you may not be able to resell your shares at or above your investment price.***

The stock market, particularly in recent years, has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. Our operating results may fluctuate from period to period for a number of reasons, and as a result our stock price may be subject to significant fluctuations. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- our financial condition, including our need for additional capital;
- results from, delays in, or discontinuation of, any of the clinical trials for our drug candidates, including delays resulting from slower than expected or suspended patient enrollment or discontinuations resulting from a failure to meet pre-defined clinical endpoints;
- announcements concerning clinical trials;
- failure or delays in entering drug candidates into clinical trials;
- failure or discontinuation of any of our research programs;
- developments in establishing new strategic alliances or with existing alliances;
- market conditions in the pharmaceutical, biotechnology and other healthcare related sectors;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- issues in manufacturing our drug candidates or drugs;
- issues with the supply or manufacturing of any devices or materials needed to manufacture or utilize our drug candidates;
- FDA or other United States or foreign regulatory actions affecting us or our industry;
- market acceptance of our drugs, when they enter the market;
- third-party healthcare coverage and reimbursement policies;

· litigation or public concern about the safety of our drug candidates or drugs;

· issuance of new or revised securities analysts' reports or recommendations;

· additions or departures of key personnel; or

· volatility in the stock prices of other companies in our industry.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert our management's time and attention.

Because the Company's common stock will be primarily traded on the OTCQB tier of the OTC Markets, the volume of shares traded and the prices at which such shares trade may result in lower prices than might otherwise exist if our common stock was traded on a national securities exchange.

The Company's shares are traded on the OTCQB tier of the OTC Markets. Stock traded on the OTCQB tier of the OTC Markets is often less liquid than stock traded on national securities exchanges, not only in terms of the number of shares that can be bought and sold at a given price, but also in terms of delays in the timing of transactions and reduced coverage of the Company by security analysts and media. This may result in lower prices for the Company's common stock than might otherwise be obtained if the common stock were traded on a national securities exchange, and could also result in a larger spread between the bid and asked prices for the Company's common stock. There is no guarantee that the Company will be able to re-list its common stock on the NASDAQ Capital Market or any other market. The Company's management will be required to devote substantial time to comply with public company regulations.

We have never paid dividends and we do not anticipate paying dividends in the future.

We have never paid dividends on our capital stock and do not anticipate paying any dividends for the foreseeable future. We anticipate that the Company will retain its earnings, if any, for future growth. Investors seeking cash dividends should not invest in the Company's common stock for that purpose.

There may be additional issuances of shares of blank check preferred stock in the future.

Our certificate of incorporation authorizes the issuance of up to 5,000,000 shares of preferred stock, none of which are issued or currently outstanding. Our Board of Directors will have the authority to fix and determine the relative rights and preferences of preferred shares, as well as the authority to issue such shares, without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that is senior to our common stock that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividends, additional registration rights, anti-dilution protection, the right to the redemption of such shares, together with other rights, none of which will be afforded holders of our common stock.

Recent turmoil in the financial markets and the global recession has adversely affected and may continue to adversely affect our industry, business and ability to obtain financing.

Recent global market and economic conditions have been unprecedented and challenging with tighter credit conditions leading to decreased spending by businesses and consumers alike. Continued turbulence in the U.S. and international markets and economies and prolonged declines in business and consumer spending may adversely affect our liquidity and financial condition, including our ability to access the capital markets to meet our liquidity needs.

We may not be able to attract the attention of major brokerage firms.

Security analysts of major brokerage firms may not provide coverage of us since there is no incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will want to conduct any secondary offerings on behalf of our Company in the future. The lack of such analyst coverage may decrease the public demand for our common stock, making it more difficult for you to resell your shares when you deem appropriate.

**** The operational and other projections and forecasts that we may make from time to time are subject to inherent risks.***

The projections and forecasts that our management may provide from time to time (including, but not limited to, those relating to timing, progress and anticipated results of clinical development, regulatory processes, clinical trial timelines and any anticipated benefits of our product candidates) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this Quarterly Report on Form 10-Q should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such. Additionally, final data may differ significantly from preliminary data reported.

Our certificate of incorporation and by-laws contain provisions that may discourage, delay or prevent a change in our management team that stockholders may consider favorable.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that may have the effect of preserving our current management, such as:

- authorizing the issuance of “blank check” preferred stock without any need for action by stockholders;
- eliminating the ability of stockholders to call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

These provisions could make it more difficult for our stockholders to affect our corporate policies, make changes in our Board of Directors and for a third party to acquire us, even if doing so would benefit our stockholders.

**** Ownership of the Company's common stock is highly concentrated, which may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the Company's stock price to decline.***

Capricor's former stockholders, many of whom are executive officers and directors continuing with the Company, together with their respective affiliates at the time of the merger between Capricor and Nile beneficially owned or controlled approximately 90% of the outstanding shares of the Company. Accordingly, stockholders, executive officers, directors and their affiliates, acting individually or as a group, will have substantial influence over the outcome of a corporate action of the Company requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the Company's assets or any other significant corporate transaction. These stockholders may also exert influence in delaying or preventing a change in control of the Company, even if such change in control would benefit the other stockholders of the Company. In addition, the significant concentration of stock ownership may adversely affect the market value of the Company's common stock due to investors' perception that conflicts of interest may exist or arise.

The Company's ability to utilize Nile's net operating loss and tax credit carryforwards in the future is subject to substantial limitations and may be further limited as a result of the recent merger with Capricor.

Federal and state income tax laws impose restrictions on the utilization of net operating loss, or NOL, and tax credit carryforwards in the event that an "ownership change" occurs for tax purposes, as defined by Section 382 of the Code. In general, an ownership change occurs when shareholders owning 5% or more of a "loss corporation" (a corporation entitled to use NOL or other loss carryforwards) have increased their aggregate ownership of stock in such corporation by more than 50 percentage points during any three-year period. If an "ownership change" occurs, Section 382 of the Code imposes an annual limitation on the amount of post-ownership change taxable income that may be offset with pre-ownership change NOLs of the loss corporation experiencing the ownership change. The annual limitation is calculated by multiplying the loss corporation's value immediately before the ownership change by the greater of the long-term tax-exempt rate determined by the IRS in the month of the ownership change or the two preceding months. This annual limitation may be adjusted to reflect any unused annual limitation for prior years and certain recognized built-in gains and losses for the year. Section 383 of the Code also imposes a limitation on the amount of tax liability in any post-ownership change year that can be reduced by the loss corporation's pre-ownership change tax credit carryforwards.

It is expected that the merger between Nile and Capricor resulted in another "ownership change" of Nile. Accordingly, the Company's ability to utilize Nile's NOL and tax credit carryforwards may be substantially limited. These limitations could, in turn, result in increased future tax payments for the Company, which could have a material adverse effect on the business, financial condition, or results of operations of the Company.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and stock price.

The Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley, as well as rules implemented by the SEC and any market on which the Company's shares may be listed in the future, impose various requirements on public companies, including those related to corporate governance practices. The Company's management and other personnel will need to devote a substantial amount of time to these requirements. Moreover, these rules and regulations will increase the Company's legal and financial compliance costs and will make some activities more time consuming and costly.

Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires that we establish and maintain an adequate internal control structure and procedures for financial reporting. Our annual reports on Form 10-K must contain an assessment by management of the effectiveness of our internal control over financial reporting and must include disclosure of any material weaknesses in internal control over financial reporting that we have identified. The requirements of Section 404 are ongoing and also apply to future years. We expect that our internal control over financial reporting will continue to evolve as our business develops. Although we are committed to continue to improve our internal control processes and we will continue to diligently and vigorously review our internal control over financial reporting in order to ensure compliance with Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. Therefore, we cannot be certain that in the future material weaknesses or significant deficiencies will not exist or otherwise be discovered. If material weaknesses or other significant deficiencies occur, these weaknesses or deficiencies could result in misstatements of our results of operations, restatements of our consolidated financial statements, a decline in our stock price, or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.

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

None.

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	Form of Warrant issued to Investors in July 2009 Private Placement (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-3, filed with the Commission on August 13, 2009).
4.2	Form of Warrant issued to Placement Agent in July 2009 Private Placement (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-3, filed with the Commission on August 13, 2009).
4.3	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).
4.4	Form of Unit Warrant issued to Investors in April 2010 Public Offering (incorporated by reference to, and included as part of, 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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	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).
4.6	Form of Warrant issued to Investors in June 2011 Private Placement (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on June 24, 2011).
4.7	Form of Warrant issued to Investors in March 2012 Registered Offering (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on April 2, 2012).
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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101	The following financial information from Capricor Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014, formatted in eXtensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of September 30, 2014 and December 31, 2013, (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2014 and September 30, 2013, (iii) Condensed Consolidated Statement of Stockholders' Equity (Deficit) for the period from December 31, 2013 through September 30, 2014, (iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2014 and September 30, 2013, and (v) Notes to Condensed Consolidated Financial Statements.*

* Filed herewith.

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: November 13, 2014 By: /s/ Linda Marbán, Ph.D.
Linda Marbán, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2014 By: /s/ Anthony Bergmann
Anthony Bergmann
Vice President of Finance
(Principal Financial and Accounting Officer)

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