

CAPRICOR THERAPEUTICS, INC.

Form 10-Q

August 15, 2016

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

**☐ Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
for the quarterly period ended June 30, 2016**

**or**

**☐ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
for the transition period from            to**

**Commission File Number: 001-34058**

**CAPRICOR THERAPEUTICS, INC.**

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



Edgar Filing: CAPRICOR THERAPEUTICS, INC. - Form 10-Q

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

As of August 12, 2016, there were 17,954,398 shares of the registrant's common stock, par value \$0.001 per share, issued and outstanding.

**INDEX TO QUARTERLY REPORT ON FORM 10-Q**

	<b>PAGES</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<u>Item 1. Financial Statements</u>	4
<u>Condensed Consolidated Balance Sheets at June 30, 2016 (unaudited) and December 31, 2015</u>	4
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)</u>	5
<u>Condensed Consolidated Statements of Stockholders' Equity (Deficit) (unaudited)</u>	6
<u>Condensed Consolidated Statements of Cash Flows (unaudited)</u>	7
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	8
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	26
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	41
<u>Item 4. Controls and Procedures</u>	42
<b><u>PART II. OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	43
<u>Item 1A. Risk Factors</u>	43
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	43
<u>Item 3. Defaults Upon Senior Securities</u>	43
<u>Item 4. Mine Safety Disclosures</u>	43
<u>Item 5. Other Information</u>	43
<u>Item 6. Exhibits</u>	44
<u>Signatures</u>	46
<u>Exhibit Index</u>	47

### Special Note Regarding Forward-Looking Statements

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

- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- expectation of or dates for commencement of clinical trials, investigational new drug filings and similar plans or projections;
  - the regulatory approval of our drug candidates;
  - our use of clinical research centers, third party manufacturers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
  - our ability to manufacture products for clinical and commercial use;
  - our ability to protect our patents and other intellectual property;
  - our ability to market any of our products;
  - our ability to compete against other companies and research institutions;
  - our ability to expand our operations internationally;
  - the effect of potential strategic transactions on our business;
- acceptance of our products by doctors, patients or payors and the availability of reimbursement for our product candidates;
  - our ability to attract and retain key personnel; and
  - the volatility of our stock price.

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

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

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

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

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

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

Edgar Filing: CAPRICOR THERAPEUTICS, INC. - Form 10-Q

TOTAL LONG-TERM LIABILITIES	12,803,672	10,572,678
TOTAL LIABILITIES	19,008,373	17,101,346
COMMITMENTS AND CONTINGENCIES (NOTE 6)		
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none issued and outstanding	-	-
Common stock, \$0.001 par value, 50,000,000 shares authorized, 17,952,323 and 16,254,985 shares issued and outstanding, respectively	17,952	16,255
Additional paid-in capital	38,988,747	34,115,052
Accumulated other comprehensive income	4,778	9,385
Accumulated deficit	(44,127,654)	(35,172,466)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(5,116,177 )	(1,031,774 )
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	\$ 13,892,196	\$ 16,069,572

See accompanying notes to the unaudited condensed consolidated financial statements.



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

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

See accompanying notes to the unaudited condensed consolidated financial statements.



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

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

See accompanying notes to the unaudited condensed consolidated financial statements.

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

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

Edgar Filing: CAPRICOR THERAPEUTICS, INC. - Form 10-Q

Cash and cash equivalents balance at end of period	\$8,851,129	\$5,038,260
----------------------------------------------------	-------------	-------------

SUPPLEMENTAL DISCLOSURES:

Interest paid in cash	\$1,343	\$2,685
Income taxes paid in cash	\$-	\$-

See accompanying notes to the unaudited condensed consolidated financial statements.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

Description of Business

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

Basis of Presentation

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

Basis of Consolidation

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

### Liquidity

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

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

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

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

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

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

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

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

Use of Estimates

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



### Cash and Cash Equivalents

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

### Restricted Cash

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

### Marketable Securities

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

### Property and Equipment

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

**CAPRICOR THERAPEUTICS, INC.****Notes to CONDENSED CONSOLIDATED financial statements****(unaudited)****1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)**

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

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

Intangible Assets

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

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

2020	4,330
Thereafter	2,165

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

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

#### Government Research Grants

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

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

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

Income from Collaboration Agreement

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

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

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

### Loan Payable

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

### Rent

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

### Research and Development

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

### Comprehensive Income (Loss)

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

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

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

Stock-Based Compensation

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

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

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

Basic and Diluted Loss per Share

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

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

Fair Value Measurements

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

Level Input: Input Definition:

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

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

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

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

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

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

Warrant Liability

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

Recent Accounting Pronouncements

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



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

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

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

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

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

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

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

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

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

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

## 2. LOAN PAYABLE

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

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

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**2. LOAN PAYABLE (continued)**

Under the terms of the CIRM Loan Agreement, if Capricor is not in default, the loan may be forgiven during the term of the project period if Capricor abandons the trial due to the occurrence of a no-go milestone. After the end of the project period, the loan may also be forgiven if Capricor elects to abandon the project under certain circumstances. Under the terms of the CIRM Loan Agreement, Capricor is required to meet certain financial milestones by demonstrating to CIRM prior to each disbursement of loan proceeds that it has sufficient funds available to cover all costs and expenses anticipated to be required to continue Phase II of the ALLSTAR trial for at least the following 12-month period, less the costs budgeted to be covered by planned loan disbursements. Capricor did not issue stock, warrants or other equity to CIRM in connection with this loan award. Additionally, on September 30, 2015, the Company entered into a Joinder Agreement with Capricor and CIRM, pursuant to which, among other things, the Company agreed to become a loan party under the CIRM Loan Agreement and to be jointly and severally responsible with Capricor for the performance of, and to be bound by the obligations and liabilities under, the CIRM Loan Agreement, subject to the rights and benefits afforded to a loan recipient thereunder.

In addition to the foregoing, 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.

The due diligence costs are recorded as a discount on the loan and amortized to general and administrative expenses over the remaining term of the loan. As of June 30, 2016, \$30,000 of loan costs were capitalized with the balance of \$8,665 to be amortized over approximately one year and seven months.

In 2013, Capricor received loan proceeds of \$3,925,066, net of loan costs. The disbursements carried an initial interest rate of approximately 2.5% - 2.8% per annum.

In 2014, Capricor received loan proceeds of \$5,194,124, which includes previously deducted due diligence costs that were refunded. The disbursements carried an initial interest rate of approximately 2.6% per annum.

In March 2016, Capricor received an additional disbursement pursuant to the terms of the loan award of \$1,000,000. This disbursement carries interest at the initial rate of approximately 3.2% per annum.

In June 2016, Capricor received an additional disbursement of \$2,000,000 pursuant to the terms of the CIRM Loan Agreement. This disbursement carries interest at the initial rate of approximately 3.3% per annum. For the three months ended June 30, 2016 and 2015, interest expense under the CIRM Loan Agreement was approximately \$76,663 and \$61,681, respectively. For the six months ended June 30, 2016 and 2015, interest expense under the CIRM Loan Agreement was approximately \$142,452 and \$123,362, respectively. The principal balance outstanding under the CIRM Loan Agreement was \$12,155,857 and \$9,155,857 as of June 30, 2016 and December 31, 2015, respectively. The balance of the loan with accrued interest is due in 2018, unless extended pursuant to the terms of the CIRM Loan Agreement.

### **3. STOCKHOLDERS' EQUITY**

#### Registered Direct Offering

On March 16, 2016, the Company issued and sold to certain investors an aggregate of 1,692,151 shares of the Company's common stock at a purchase price of \$2.40 per share for an aggregate purchase price of approximately \$4,060,000. This offering included participation from the Company's officers and directors. Fees paid in conjunction with the registered direct offering, which included placement agent fees and estimated offering expenses, amounted to approximately \$144,629 in the aggregate and were recorded as a reduction to additional paid-in capital, resulting in net proceeds of approximately \$3.9 million.

In connection with the sale of shares of the Company's common stock, on March 16, 2016, the Company also issued and sold to the investors, in a concurrent private placement, warrants to purchase up to an aggregate of 846,073 shares of the Company's common stock. Each warrant has an exercise price of \$4.50 per share, will initially be exercisable on September 17, 2016, and will expire on March 16, 2019. Pursuant to the terms of each warrant, if, on or after the original exercise date of such warrant, the Volume Weighted Average Price of the Common Stock (as defined in each warrant) equals or exceeds \$7.50 per share for any period of 20 consecutive trading days, the Company shall have the right, but not the obligation, to redeem any unexercised portion of such warrant for a redemption fee of \$0.001 per share of common stock underlying such warrant.

#### Outstanding Shares

At June 30, 2016, the Company had 17,952,323 shares of common stock issued and outstanding.



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

The following table summarizes all warrant activity for the six month period ended June 30, 2016:

	Warrants	Weighted Average Exercise Price
Outstanding at January 1, 2016	235,830	\$ 2.27
Granted	846,073	4.50
Exercised	-	-
Expired	-	-
Outstanding at June 30, 2016	1,081,903	\$ 4.01

The following table summarizes all outstanding warrants to purchase shares of the Company's common stock as of June 30, 2016:

At June 30, 2016			
Grant Date	Warrants Outstanding	Exercise Price	Expiration Date
4/4/2012	187	\$ 2.27	4/4/2017
11/20/2013	235,643	\$ 2.27	11/20/2018
3/16/2016	846,073	\$ 4.50	3/16/2019
	1,081,903		

The March 2016 warrants will initially become exercisable on September 17, 2016.

### 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 superseded the 2006 Stock Option Plan) (the "2012 Plan"), and (iv) the 2012 Non-Employee Director Stock Option Plan (the "2012 Non-Employee Director Plan").

On August 10, 2005, the Company adopted the 2005 Plan. On July 26, 2010, the Company's stockholders approved an amendment to the 2005 Plan increasing the total number of shares authorized for issuance thereunder to 190,000. Under the 2005 Plan, incentives were permitted to be granted to officers, employees, directors, consultants and advisors. Incentives under the 2005 Plan were 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. The 2005 Plan will remain in effect until all incentives granted under the 2005 Plan have either been satisfied by the issuance of shares of common stock or the payment of cash or been terminated under the terms of the 2005 Plan and all restrictions imposed on shares of common stock in connection with their issuance under the 2005 Plan have lapsed. However, no additional incentives may be granted under the 2005 Plan after the tenth anniversary of the date the 2005 Plan was approved by the Company's stockholders.



**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**4. STOCK AWARDS, WARRANTS AND OPTIONS (continued)**

At the time the merger between Capricor and Nile became effective, 4,149,710 shares of common stock were reserved under the 2012 Plan for the issuance of stock options, stock appreciation rights, restricted stock awards and performance unit/share awards to employees, consultants and other service providers. Included in the 2012 Plan are the shares of common stock that were originally reserved under the 2006 Stock Option Plan. Under the 2012 Plan, each stock option granted will be designated in the award agreement as either an incentive stock option or a nonstatutory stock option. Notwithstanding such designation, however, to the extent that the aggregate fair market value of the shares with respect to which incentive stock options are exercisable for the first time by the participant during any calendar year (under all plans of the Company and any parent or subsidiary) exceeds \$100,000, such options will be treated as nonstatutory stock options. On June 2, 2016 at the Company's annual stockholder meeting, the stockholders approved a proposal to amend the 2012 Plan, to, among other things, increase the number of shares of common stock of the Company that may be issued under the 2012 Plan to equal the sum of 4,149,710 plus 2% of the outstanding shares of common stock as of December 31, 2015, with the number of shares that may be issued under the 2012 Plan automatically increasing thereafter on January 1 of each year, commencing with January 1, 2017, by 2% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year (rounded down to the nearest whole share). Additionally, in connection with the proposed increase in the total number of shares of common stock that may be issued under the 2012 Plan, the Company increased the number of shares of common stock that may be issued pursuant to options that are intended to qualify as incentive stock options from 4,149,710 shares to 4,474,809 shares.

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

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

Edgar Filing: CAPRICOR THERAPEUTICS, INC. - Form 10-Q

The estimated weighted average fair values of the options granted during the three months ended June 30, 2016 and 2015 were approximately \$2.15 and \$3.53 per share, respectively. The estimated weighted average fair values of the options granted during the six months ended June 30, 2016 and 2015 were approximately \$2.00 and \$4.15 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 six months ended June 30, 2016 and 2015:

	June 30, 2016	June 30, 2015
Expected volatility	79% - 80%	81% - 82%
Expected term	5 - 7 years	5 - 7 years
Dividend yield	0%	0%
Risk-free interest rates	0.5% - 1.7%	0.3% - 2.0%

Employee and non-employee stock-based compensation expense for the three and six months ended June 30, 2016 and 2015 was as follows:

	Three months ended		Six months ended	
	June 30, 2016	2015	June 30, 2016	2015
General and administrative	\$471,761	\$259,930	\$691,085	\$788,454
Research and development	182,264	83,000	253,526	126,597
Total	\$654,025	\$342,930	\$944,611	\$915,051

As of June 30, 2016, the total unrecognized fair value compensation cost related to non-vested stock options was approximately \$4.6 million, which is expected to be recognized over approximately 2.8 years.

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

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 is a schedule summarizing employee and non-employee stock option activity for the six months ended June 30, 2016:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at January 1, 2016	5,997,323	\$ 1.59	\$8,876,038
Granted	750,000	2.88	
Exercised	(5,187 )	0.19	
Expired/Cancelled	(91,407 )	7.68	
Outstanding at June 30, 2016	6,650,729	\$ 1.65	\$15,296,677
Exercisable at June 30, 2016	4,920,755	\$ 0.90	\$15,008,303

The aggregate intrinsic value represents the difference between the exercise price of the options and the estimated fair value of the Company's common stock for each of the respective periods.

The aggregate intrinsic value of options exercised was approximately \$12,086 for the six months ended June 30, 2016.

## 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, cash equivalents and marketable securities. As of June 30, 2016, the Company maintained approximately \$11.5 million of uninsured deposits.

## 6. COMMITMENTS AND CONTINGENCIES

### CIRM Grant Award

On June 16, 2016, Capricor entered into the CIRM Award with CIRM in the amount of approximately \$3.4 million to fund, in part, Capricor's Phase I/II HOPE-Duchenne clinical trial investigating CAP-1002 for the treatment of Duchenne muscular dystrophy-associated cardiomyopathy. Pursuant to terms of the CIRM Award, the disbursements will be tied to the achievement of specified operational milestones. If CIRM determines, in its sole discretion, that Capricor has not complied with the terms and conditions of the CIRM Award, CIRM may suspend or permanently cease disbursements or pursue other remedies as allowed by law. In addition, the terms of the CIRM Award include a co-funding requirement pursuant to which Capricor is required to spend approximately \$2.3 million of its own capital to fund the HOPE-Duchenne clinical trial. If Capricor fails to satisfy its co-funding requirement, the amount of the CIRM Award may be proportionately reduced. The CIRM Award is further subject to the conditions and requirements set forth in the CIRM Grants Administration Policy for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, CCR Sections 100600-100612, and the sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from CIRM funded research as set forth in Title 17, CCR Section 100608. The maximum royalty on net commercial revenue that Capricor may be required to pay to CIRM is equal to nine times the total amount awarded and paid to Capricor.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**6. COMMITMENTS AND CONTINGENCIES (continued)**

After completing the CIRM funded research project and after the award period end date, estimated to be in late 2017 or in 2018, Capricor has the right to treat the CIRM Award as a loan, the terms of which will be determined based on various factors, including the stage of the research and the stage of development at the time the election is made. On June 20, 2016, Capricor entered into a Loan Election Agreement with CIRM whereby, among other things, CIRM and Capricor agreed that, if converted, the term of the loan would be five years from the date of execution of the applicable loan agreement; provided that the term of the loan will not exceed ten years from the date on which the CIRM Award was granted. Beginning on the date of the loan, the loan shall bear interest on the unpaid principal balance plus the interest that was accrued prior to the election point according to the terms set forth in CIRM's Loan Policy ("New Loan Balance") at a per annum rate equal to the LIBOR rate for a three-month deposit in U.S. dollars, as published by the Wall Street Journal on the loan date, plus one percent. Interest shall be compounded annually on the outstanding New Loan Balance commencing with the loan date and the interest shall be payable, together with the New Loan Balance, upon the due date of the loan. If Capricor elects to treat the CIRM Award as a loan, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements. Capricor will not make its decision as to whether it will elect to convert the CIRM Award into a loan until after the end of the HOPE-Duchenne trial. Since Capricor may be required to repay some or all of the amounts awarded by CIRM, the Company will account for this award as a liability rather than revenue. If Capricor were to lose this funding, it may be required to delay, postpone, or cancel its HOPE-Duchenne trial or otherwise reduce or curtail its operations, unless it was able to obtain adequate financing for its clinical trial from additional sources. In July 2016, Capricor received the first disbursement of \$2.0 million under the terms of the CIRM Award.

Leases

Capricor leases space for its corporate offices pursuant to a lease that was originally effective for a two year period beginning July 1, 2013 with an option to extend the lease for an additional twelve months. The monthly lease payment was \$16,620 per month for the first twelve months of the term and increased to \$17,285 per month for the second twelve months of the term. On March 3, 2015, Capricor executed a Second Amendment to Lease with The Bubble Real Estate Company, LLC, pursuant to which (i) additional space was added to the Company's corporate office lease and (ii) the Company exercised its option to extend the lease term through June 30, 2016. Under the terms of the Second Amendment, commencing February 2, 2015, the base rent was \$17,957 for one month, and, commencing March 2, 2015, the base rent increased to \$21,420 per month for four months. Commencing July 1, 2015, the base rent increased to \$22,111 per month for the remainder of the lease term. On May 25, 2016, Capricor entered into a Third Amendment to Lease (the "Third Amendment") with The Bubble Real Estate Company, LLC. Under the terms of the

Third Amendment, the lease term commenced on July 1, 2016 and will end on December 31, 2018. Commencing July 1, 2016, the base rent increased to \$22,995 per month for the first twelve months of the term, will increase to \$23,915 per month for the second twelve months of the term, and, thereafter, will increase to \$24,872 for the remainder of the lease 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 under the Facilities Lease was approximately \$15,461 per month for the first six months of the term and increased to approximately \$19,350 per month for the remainder of the term. The amount of rent expense is subject to annual adjustments according to increases in the Consumer Price Index.

Unless renewed, each of the leases described above will not be in effect for fiscal year 2019. A summary of future minimum rental payments required under operating leases as of June 30, 2016 is as follows:

Years ended	Operating Leases
2016 (6 months)	\$254,070
2017	378,210
2018	292,722
Total minimum lease payments	\$925,002

Expense incurred under operating leases to unrelated parties was approximately \$65,088 for each of the three month periods ended June 30, 2016 and 2015, and approximately \$130,176 and \$125,765 for the six months ended June 30, 2016 and 2015, respectively. Expense incurred under operating leases to related parties was approximately \$56,105 for each of the three month periods ended June 30, 2016 and 2015, and approximately \$112,211 for each of the six month periods ended June 30, 2016 and 2015.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**6. COMMITMENTS AND CONTINGENCIES (continued)**

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 June 30, 2016.

**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.

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. In May 2015, Capricor paid the development milestone related to Phase I that was owed to JHU pursuant to the terms of the JHU License Agreement.



**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**7. LICENSE AGREEMENTS (continued)**

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 Agreements*

*License Agreement for CDCs*

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

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

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

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

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

On August 5, 2016, Capricor and CSMC entered into a Second Amendment to the Amended CSMC License Agreement, pursuant to which the parties agreed to add certain patent families to the schedule of patent rights set forth in the agreement. Under the Second License Amendment, (i) the description of patent rights in Schedule A has been replaced by a Revised Schedule A that includes two additional patent family applications; (ii) Capricor will be required to pay CSMC an upfront fee of \$2,500; and (iii) Capricor will be required to reimburse CSMC approximately \$10,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent families.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**7. LICENSE AGREEMENTS (continued)**

*License Agreement for Exosomes*

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

Pursuant to the Exosomes License Agreement, CSMC was paid a license fee and Capricor reimbursed CSMC for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor is required to meet certain non-monetary development milestones and is obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a single-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third party for patent rights in connection with the royalty bearing product.

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

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

On June 10, 2015, Capricor and CSMC entered into a Second Amendment to Exosomes License Agreement, thereby amending the Exosomes License Agreement further to add an additional patent application to the Schedule of Patent Rights.

On August 5, 2016, Capricor and CSMC entered into a Third Amendment to the Exosomes License Agreement (the “Third Exosomes License Amendment”) pursuant to which the parties agreed to add certain patent families to the schedule of patent rights under the agreement. Under the Third Exosomes License Amendment, (i) the description of patent rights in Schedule A has been replaced by a Revised Schedule A that includes two additional patent family applications; (ii) Capricor will be required to pay CSMC an upfront fee of \$2,500; and (iii) Capricor will be required to reimburse CSMC approximately \$16,000 for attorneys’ fees and filing fees that were incurred in connection with the additional patent families.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**7. LICENSE AGREEMENTS (continued)**

*Collaboration Agreement with Janssen Biotech, Inc.*

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

Company Technology – Cenderitide and CU-NP

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

*Mayo License Agreement*

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

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

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**7. LICENSE AGREEMENTS (continued)**

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

*Medtronic Clinical Trial Funding Agreement*

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

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

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

Transfer Agreement, described below.

*Medtronic Transfer Agreement*

On October 8, 2014, the Company entered into a Transfer Agreement (the “Transfer Agreement”) with Medtronic to acquire patent rights relating to the formulation and pump delivery of natriuretic peptides. Pursuant to the Transfer Agreement, Medtronic has assigned to the Company all of its right, title and interest in all natriuretic peptide patents and patent applications previously owned by Medtronic or co-owned by Medtronic and the Company (“Natriuretic Peptide Patents”). Under the Transfer Agreement, the Company received all rights to the Natriuretic Peptide Patents, including the right to grant licenses and to make assignments without approval from Medtronic.

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

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

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



**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**8. RELATED PARTY TRANSACTIONS**

Lease and Sub-Lease Agreements

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

On April 1, 2013, Capricor entered into a sublease with Reprise Technologies, LLC, a limited liability company which is wholly owned by Dr. Litvack, the Company’s Executive Chairman and member of its Board of Directors, for \$2,500 per month. The sublease is on a month-to-month basis. For each of the three month periods ended June 30, 2016 and 2015, Capricor recognized \$7,500 in sublease income from the related party. For each of the six month periods ended June 30, 2016 and 2015, Capricor recognized \$15,000 in sublease income from the related party. Sublease income is recorded as a reduction to general and administrative expenses.

Consulting Agreements

Effective January 1, 2013, Frank Litvack, the Company’s Executive Chairman and a member of its Board of Directors, entered into an oral Consulting Agreement with Capricor whereby Capricor agreed to pay Dr. Litvack fees of \$10,000 per month for consulting services. On March 24, 2014, Capricor entered into a written Consulting Agreement with Dr. Litvack memorializing the \$10,000 per month compensation arrangement described above. The agreement is terminable upon 30 days’ notice.

Payables to Related Party

At June 30, 2016 and December 31, 2015, the Company had accounts payable and accrued expenses to related parties totaling \$546,725 and \$352,334, respectively. CSMC accounts for approximately \$535,604 and \$352,334 of the accounts payable and accrued expenses to related parties as of June 30, 2016 and December 31, 2015, respectively.

## **9.SUBSEQUENT EVENTS**

### CIRM Grant Award for HOPE Clinical Trial

On July 12, 2016, Capricor received its first disbursement of \$2.0 million under the terms of the CIRM Award disbursement schedule.

### Additional CIRM Loan Disbursement for ALLSTAR Clinical Trial

On August 3, 2016, Capricor received an additional disbursement pursuant to the terms of the CIRM Loan Agreement for \$1.75 million.

## **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 discovering, developing and commercializing innovative therapies, focusing on cardiovascular disease as well as exploring other indications. Our executive offices are located at 8840 Wilshire Blvd., 2<sup>nd</sup> Floor, Beverly Hills, California 90211. Our telephone number is (310) 358-3200 and our Internet address is [www.capricor.com](http://www.capricor.com).

### **Consummation of the Merger**

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

Capricor, our wholly-owned subsidiary, was founded in 2005 as a Delaware corporation based on the innovative work of its founder, Eduardo Marbán, M.D., Ph.D., and his collaborators. First located in Baltimore, Maryland, adjacent to

The Johns Hopkins University, or JHU, where Dr. Marbán was chief of cardiology, Capricor moved to Los Angeles, California in 2007 when Dr. Marbán became Director of the Heart Institute at Cedars-Sinai Medical Center, or CSMC. Capricor's laboratories are located in space that Capricor leases from CSMC. Capricor manufactures its CAP-1002 and exosomes product candidates in manufacturing facilities provided by CSMC.

### ***Drug Candidates***

We have six drug candidates in various stages of development. Our regenerative medicine technology is the focus of our current research and development efforts, and includes CAP-1002 (allogeneic cardiosphere-derived cells, or CDCs) and CAP-2003 (CDC exosomes). CAP-1002 is the subject of two ongoing clinical trials, and we expect to enter CAP-2003 into clinical development in 2017. CAP-1001 (autologous CDCs) is a predecessor to CAP-1002 and is not in active development. Both CAP-1002 and CAP-1001 are derived from CSps (cardiospheres), and we do not plan to develop CSps as a therapeutic. We have recently conducted clinical studies with Cenderitide (CD-NP), which, together with CU-NP, composes our natriuretic peptide receptor technology, and we are currently exploring out-licensing opportunities for this technology.

**CAP-1002:** We are currently conducting two clinical trials of our lead product candidate, CAP-1002: the Phase II portion of the Phase I/II ALLSTAR trial in patients who have had a myocardial infarction (MI, also known as a heart attack), and the Phase I/II HOPE-Duchenne trial in patients with Duchenne muscular dystrophy (DMD)-associated cardiomyopathy. We have recently completed the Phase I portion of the Phase I/II DYNAMIC trial in patients with advanced heart failure.

### **Phase I/II ALLSTAR Clinical Trial**

The Phase I portion of the ALLSTAR trial was a 14-patient, open-label, dose-escalation study that was conducted to evaluate the clinical safety of CAP-1002. Each patient received a single infusion of CAP-1002 into the coronary artery most closely associated with the territory of their MI, at a dose level of either 12.5 million or 25 million cells. The primary safety endpoints focused on the potential adverse effects of CAP-1002 delivery, including potential immunologic consequences of infusing cells that had originated from an unrelated donor. Enrollment was completed in October 2013. At one and 12 months following CAP-1002 infusion, event rates observed for each of the four pre-specified safety endpoints (acute myocarditis possibly attributable to CAP-1002; death due to ventricular tachycardia or ventricular fibrillation; sudden death; and major adverse cardiac events) were 0%.

Preliminary 12-month magnetic resonance imaging (MRI) data revealed that those Phase I patients who would be eligible for randomization into the Phase II clinical study by virtue of dose and tissue type compatibility exhibited a reduction in infarct, or scar, size of 20.7% from baseline. These data also indicated a 5.2% improvement in ejection fraction, a global measure of the heart's pumping ability, from baseline. Measurements of viable mass and regional function also showed quantifiable improvements. This Phase I study was funded in large part by a grant received from the National Institutes of Health, or NIH.

In December 2013, the Gene and Cell Therapy Data Safety Monitoring Board of the National Heart Lung and Blood Institute, or the NHLBI, recommended that enrollment commence in the Phase II portion of ALLSTAR.

We began enrollment of the ongoing Phase II ALLSTAR study in the first quarter of 2014. This randomized, double-blind, placebo-controlled trial is designed to determine if treatment with CAP-1002 can reduce scar size in patients who have suffered an MI. At the time of recruitment, patients are stratified into one of two cohorts according to the time since the occurrence of their MI event (either 30-90 days post MI, or 90 days to one-year post MI). As such, CAP-1002 is being evaluated in the setting of both acute MI, in which the scar has recently formed, and chronic MI, in which the scar is more established. Patients are randomized in a 2:1 ratio to receive an infusion of CAP-1002 (25 million cells) or placebo, respectively, into the coronary artery most closely associated with the territory of their MI. The trial is powered to detect a reduction in scar size as measured by MRI in both groups of patients at the one year follow-up. In addition to evaluating CAP-1002 according to changes in scar size, ALLSTAR will also evaluate CAP-1002 according to a variety of clinical and quality of life endpoints.

Based on information available to us at the start of enrollment into the Phase II ALLSTAR trial, we initially designed this study to enroll up to 300 patients. We recently completed statistical modelling of the design of ALLSTAR which incorporated the expanded dataset that has become available from other clinical trials of our CDCs. Based on these modelling results, we have elected to decrease the enrollment goal of ALLSTAR to approximately 120 patients, a sample size that is expected to maintain sufficient statistical power to detect a reduction in scar size as measured by MRI at 12 months. We have amended our clinical protocol to reflect these changes, which amendment was approved by the Data Safety Monitoring Board and was submitted to the U.S. Food and Drug Administration, or the FDA, in February 2016. Phase II of the ALLSTAR study is being funded in large part through the support of the California Institute for Regenerative Medicine, or CIRM.

In December 2013, Capricor entered into a Collaboration Agreement and Exclusive License Option with Janssen Biotech, Inc., or Janssen. Under the agreement, Janssen has an exclusive option to enter into an exclusive license agreement with Capricor, pursuant to which, if exercised, Janssen would receive a worldwide, exclusive license to exploit CAP-1002 as well as certain allogeneic cardiospheres and cardiosphere-derived cells in the field of cardiology, except as may otherwise be agreed with respect to certain indications as may be determined. 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. We expect to receive Janssen's decision with respect to this option in the first half of 2017 following the delivery of the six-month results from the ALLSTAR trial.

*Phase I/II HOPE-Duchenne Clinical Trial*

We are currently conducting the randomized, multi-center Phase I/II HOPE-Duchenne clinical trial which is designed to evaluate the safety and preliminary efficacy of CAP-1002 in approximately 24 patients with cardiomyopathy associated with DMD. Patients are randomized in a 1:1 ratio to receive either CAP-1002 or usual care available for DMD-associated cardiomyopathy. In patients receiving CAP-1002, a dose of 25 million cells will be infused into each of the three main coronary arteries (75 million cells total), which will allow for CAP-1002 to be delivered to large areas of the myocardium. Efficacy will be evaluated according to several metrics, including cardiac MRI. We expect to complete enrollment of the HOPE-Duchenne trial in the third quarter of 2016 and to report top-line six-month results in the first quarter of 2017. This study is funded in part through a grant award from CIRM in the amount of approximately \$3.4 million. In April 2015, the FDA granted Orphan Drug designation to CAP-1002 for the treatment of DMD.

*Phase I/II DYNAMIC Clinical Trial*

The Phase I/II DYNAMIC trial, of which the Phase I portion has concluded, is designed to evaluate the safety and efficacy of CAP-1002 in the treatment of patients with advanced heart failure resulting from dilated cardiomyopathy of either ischemic or non-ischemic origin. This condition is characterized by chronic structural and functional abnormalities present throughout the heart's contractile tissue. In the DYNAMIC trial, CAP-1002 is infused into all three main coronary arteries to obtain broad exposure.

We initiated the open-label, dose-escalating Phase I portion of the DYNAMIC trial in December 2014 at a single center, and in April 2015 completed enrollment with 14 patients with New York Heart Association (NYHA) Class III heart failure. Each patient was administered CAP-1002 via a one-time, triple coronary infusion at one of several evenly-divided dose levels (37.5 million, 50 million, 62.5 million, or 75 million cells total). Initial top-line six-month results were presented at the American Heart Association's Annual Scientific Sessions in November 2015. Multi-vessel intracoronary infusion of CAP-1002 in subjects with dilated cardiomyopathy was shown to be safe in this study with no major adverse cardiac events reported at one month or at six months post-infusion. Although this trial was intended as a safety study, the six-month data demonstrated encouraging and congruent preliminary efficacy signals in multiple parameters, including subjective well-being, exercise capacity, ejection fraction and ventricular volumes.

In June 2016, Capricor reported positive 12-month data from this study. For the 12 patients available for follow-up at one year, improvements from baseline in key cardiac function and dimensional indices that had been observed at six months were directionally maintained. Importantly, the change in median left ventricular ejection fraction from baseline to 12 months maintained its level of statistical-significance at six months ( $p=0.02$  at both time points) and, on an absolute basis, continued to improve from six to 12 months. Of the five NYHA Class III subjects who received the highest dose of CAP-1002 (75 million cells), two subjects improved by two Classes (to Class I) and three improved by one Class (to Class II) at six months. At 12 months, three of these five subjects were assessed as Class I and two as Class II, demonstrating further improvement and indicating durability of the benefit of CAP-1002 on heart failure status for as long as one year following administration. CAP-1002 infusion was well-tolerated in DYNAMIC. Two of the 14 patients, who were in the lower two of the four dose cohorts, died from progressive heart failure approximately one and three months prior to study conclusion.

The DYNAMIC trial's Data Safety Monitoring Board has recommended that enrollment commence in the Phase II portion. Although we have designed a Phase II study, at this time, we have not made a determination with respect to conducting the Phase II portion of the DYNAMIC trial.

Capricor was awarded a grant for approximately \$2.9 million from the NIH to support further development of the CAP-1002 product. In June 2014, we received approval from the NIH to use the funds from the grant for the first part of the DYNAMIC trial, which we sponsored.

**CAP-2003 (CDC-Exosomes):** Exosomes are nano-sized, membrane-enclosed vesicles, or “bubbles” that are secreted by cells and contain bioactive molecules, including proteins, RNAs and microRNAs. They act as messengers to regulate the functions of neighboring cells, and pre-clinical research has shown that exogenously-administered exosomes can direct or, in some cases, re-direct cellular activity, supporting their therapeutic potential. Their size, ease of crossing cell membranes, and ability to communicate in native cellular language makes them an exciting class of potential therapeutic agents. CAP-2003 consists of exosomes secreted by CDCs, and is believed to mediate many of the effects that are observed with these cells, including anti-inflammatory, anti-angiogenic, anti-apoptotic, and anti-fibrotic effects. We are currently conducting pre-clinical studies to explore the possible therapeutic benefits that exosomes may possess, with a focus on ophthalmologic, dermatologic and oncologic disease. We expect to submit an Investigational New Drug application for CAP-2003 in the first half of 2017 and to initiate clinical development in ocular graft-versus-host disease in 2017.

**CAP-1001:** CAP-1001 consists of autologous CDCs. This product was evaluated in the randomized, double-blind, placebo-controlled Phase I CADUCEUS clinical trial in patients who had recently experienced an MI. The study was sponsored and conducted by CSMC in collaboration with JHU. Of the 25 patients enrolled, 17 received an intracoronary infusion of CAP-1001 and eight received standard of care. 16 of the 17 patients treated with CAP-1001 showed a mean reduction of approximately 45% in scar mass and an increase in viable heart muscle at one-year post heart attack. The eight patients in the control group had no significant change in scar size. The data from CADUCEUS, using autologous CDCs, suggests that CDCs are effective in reducing scar size within several months of a heart attack. The design of our ongoing ALLSTAR trial of CAP-1002, an allogeneic product, is supported by the results of CADUCEUS. In addition, ALLSTAR is evaluating the potential efficacy of CAP-1002 in patients between 90 days and one year post-MI, a patient population that CADUCEUS was not designed to study. At present, there is no plan for another clinical trial for CAP-1001.



**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 we consider the CSps an important asset, at present there is no plan to develop CSps as therapeutic agents.

**Cenderitide (CD-NP):** Cenderitide belongs to a class of drugs called natriuretic peptides. Preclinical and clinical data have shown that the natriuretic peptide class can act on multiple disease processes that play a role in negative outcomes associated with heart failure. Cenderitide's treatment goal and target indication is to provide a novel and effective therapeutic option for the outpatient treatment of heart failure, thereby addressing a critical unmet need. Cenderitide is being developed as an outpatient therapy to be delivered continuously using a validated subcutaneous infusion pump for up to 90 days (the "post-acute" period) following an acute heart failure hospital admission, as well as for other potential indications. Cenderitide was designed by scientists at the Mayo Clinic to be an agonist of both the A- and B-type natriuretic peptide receptors. In October 2014, we entered into an Agreement for Investigator-Initiated Research Support with Insulet Corporation, or Insulet, pursuant to which Insulet supported Capricor's research by engaging in certain product development, project management and design control activities, in addition to supplying the OmniPod product being used in our current studies. In 2015, we completed a Phase II study in 14 patients with stable, chronic heart failure. Patients received up to eight consecutive days of Cenderitide through subcutaneous infusion using Insulet's drug delivery system based on the OmniPod technology. This open-label trial assessed the safety, tolerability, pharmacokinetic profiles and pharmacodynamic response to increasing dose levels of Cenderitide administered in a stepwise fashion. The drug was well-tolerated and there were no significant adverse events. Capricor has recently completed an additional study to further assess the safety, tolerability, pharmacokinetic profiles and pharmacodynamic response to increasing dose levels of Cenderitide in patients with stable heart failure with moderate renal impairment. Capricor will determine the future strategy for the development of Cenderitide, which may include exploring potential out-licensing arrangements. Cenderitide has been granted Fast-Track designation by the FDA in the post-acute period.

**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. 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 several 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 explore other potential indications for CAP-1002, and as we further develop Cenderitide, exosomes and 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 to date have been proceeds from private and public equity sales, grants received from the NIH, a payment from Janssen and a loan and grant award from CIRM.

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

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

Our results have included non-cash compensation expense due to the issuance of stock options and warrants, as applicable. We expense the fair value of stock options and warrants over their vesting period as applicable. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial performance and product development. Stock-based compensation expense is included in the consolidated statements of operations under G&A or R&D expenses, as applicable. We expect to record additional non-cash compensation expense in the future, which may be significant.

## Results of Operations

*General and Administrative Expenses.* General and administrative, or G&A, expenses for the three months ended June 30, 2016 and 2015 were approximately \$1.4 million and \$0.9 million, respectively. The increase in the second quarter of 2016 of approximately \$0.5 million compared to the same period of 2015 is primarily attributable to an increase of approximately \$0.2 million related to stock-based compensation expense and approximately \$0.2 million in investor relations and other corporate business expenses. Furthermore, there was an increase of approximately \$0.1 million in compensation related to increased headcount and salaries in the three months ended June 30, 2016 as compared to the same period of 2015.

G&A expenses for the six months ended June 30, 2016 and 2015 were approximately \$2.5 million and \$2.3 million, respectively. The increase during the first six months of 2016 of approximately \$0.2 million compared to the same period of 2015 is primarily attributable to an increase of approximately \$0.1 million related to investor relations and other corporate business expenses. Furthermore, there was an increase of approximately \$0.2 million in compensation related to increased headcount, salaries, and recruiting and a decrease of approximately \$0.1 million related to stock-based compensation in the six months ended June 30, 2016 as compared to the same period of 2015.

*Research and Development Expenses.* Research and development, or R&D, expenses for the three months ended June 30, 2016 and 2015 were approximately \$4.3 million and \$3.4 million, respectively. The increase of approximately \$0.9 million in the second quarter of 2016 over the same period of 2015 is primarily due to clinical development activities of CAP-1002 (ALLSTAR and HOPE-Duchenne) and other continued research and development efforts. These activities resulted in an increase of approximately \$0.6 million in clinical costs primarily related to contract research organizations and manufacturing for CAP-1002, as well as patient costs and expenses for the operation team that supports our clinical trials. Additionally, for the three months ended June 30, 2016, there was an increase of approximately \$0.4 million in R&D expenses related to our product candidates, including exosomes. Furthermore, there was a decrease of approximately \$0.2 million in clinical costs associated with our DYNAMIC and Cenderitide clinical trials and an increase of \$0.1 million in stock-based compensation expense during the second quarter of 2016 compared to the same period of 2015.

R&D expenses for the six months ended June 30, 2016 and 2015 were \$8.6 million and \$7.2 million, respectively. The increase of approximately \$1.4 million in the first half of 2016 over the same period of 2015 is primarily due to the clinical development activities of CAP-1002 (ALLSTAR and HOPE-Duchenne) and other continued research and development efforts. These activities resulted in an increase of approximately \$1.5 million in clinical costs primarily related to contract research organizations and manufacturing for CAP-1002, as well as patient costs and expense for the operation team that supports our clinical trials. Additionally, for the six months ended June 30, 2016, there was an increase of approximately \$0.6 million in R&D expenses related to our product candidates, including exosomes. Furthermore, there was a decrease of approximately \$0.8 million in clinical costs associated with our DYNAMIC and Cenderitide clinical trials and an increase of \$0.1 million in stock-based compensation expense during the second half of 2016 compared to the same period of 2015.

*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. We expect to spend approximately \$10.0 million to \$13.0 million during 2016 on the development and manufacturing of CAP-1002, which expenses are primarily related to our Phase II ALLSTAR trial, the HOPE-Duchenne trial and the DYNAMIC trial. We began enrollment of the Phase II portion of the ALLSTAR trial in the first quarter of 2014. Additionally, we have now completed statistical modelling of the design of ALLSTAR. This modelling incorporated the expanded dataset that has become available from other clinical trials with our CDCs. Based on the results, we have elected to decrease the enrollment goal of ALLSTAR to approximately 120 patients, a sample size that is expected to maintain sufficient statistical power to detect a reduction in scar size as measured by MRI at twelve months. We have amended our clinical protocol to reflect these changes, which amendment has been approved by the Data Safety Monitoring Board and submitted to the FDA in February 2016. Phase II is funded in large part through the support of a loan award from CIRM. The trial will measure several endpoints, including scar size. Additional endpoints include left ventricular end-systolic and diastolic volume and ejection fraction at six and twelve months. In regards to the DYNAMIC trial, Capricor recently announced positive 12-month data from the DYNAMIC trial. DYNAMIC was funded in large part through a grant award from the NIH.

Except as may otherwise be agreed with respect to certain indications as may be determined, if Janssen exercises its exclusive option under the Collaboration Agreement and Exclusive License Option between the Company and Janssen, or the Janssen Agreement, 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, except as may otherwise be agreed with respect to certain indications as may be determined, Janssen will thereafter be responsible for any additional trials and future development costs with respect to CAP-1002. Furthermore, as we proceed with the HOPE-Duchenne trial, which is designed to evaluate the treatment of cardiac dysfunction associated with DMD, we expect our expenses related to CAP-1002 to increase further. Our strategy for further development of CAP-1002 will depend to a large degree on the outcome of these planned studies and on Janssen's decision with respect to the option.

*Cenderitide* – We acquired the rights to Cenderitide in 2006, and have incurred substantial losses surrounding the development of the product to date. Prior to the merger between Capricor and Nile, Nile had incurred approximately \$19.9 million in expenses directly relating to the Cenderitide development program through September 30, 2013. In March 2015, we completed enrollment of the Phase II trial, which enrolled 14 patients with stable, chronic heart failure. Capricor initiated an additional small study in 2016 to further assess the safety and efficacy of this product candidate, which will include higher dose levels of Cenderitide. We expect to spend approximately \$0.5 million to \$1.0 million during 2016 in development expenses related to the Cenderitide clinical program. Capricor will determine the future strategy for the development of Cenderitide, which may include exploring potential out-licensing arrangements.

*Exosomes* – Exosomes are nano-sized, membrane-enclosed vesicles, or “bubbles”, that are filled with select molecules, including proteins, RNAs and microRNAs, which, when released, send messages to neighboring cells to regulate cellular functions. We expect to spend approximately \$2.0 million to \$3.0 million during 2016 in pre-clinical expenses related to the exosomes program. Capricor is currently engaged in pre-clinical testing of exosomes to explore their therapeutic potential.

*CAP-1001* – In 2011, CSMC, in collaboration with JHU, completed the Phase I CADUCEUS trial. This study enrolled 25 patients who had suffered a heart attack within a mean of 65 days. Seventeen patients received CAP-1001 and eight received standard of care. Twelve months after the study had completed, no measurable adverse 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 scar size. While these data support CAP-1002 development as is currently being conducted through the ongoing Phase II ALLSTAR trial, at present there is no plan to conduct another clinical trial of CAP-1001.

*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 candidate.

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

Our expenditures on current and future clinical development programs, particularly our CAP-1002, Cenderitide and exosomes programs, are expected to be substantial and to increase in relation to our available capital resources. However, these planned expenditures are subject to many uncertainties, including the results of clinical trials and whether we develop any of our product candidates independently or with a partner. As a result, we cannot predict with any significant degree of certainty the amount of time which will be required to complete our clinical trials, the costs of completing research and development projects or whether, when and to what extent we will generate revenues from

the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during manufacturing and clinical development and as a result of a variety of other factors, including:

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

*Grant Income.* Grant income for the three months ended June 30, 2016 and 2015 was approximately \$0.2 million and \$0.4 million, respectively. The decrease in grant income of approximately \$0.2 million in the second quarter of 2016 as compared to the second quarter of 2015 is due to the timing of activities associated with the DYNAMIC clinical trial. During the second quarter of 2015, the DYNAMIC clinical trial was actively enrolling patients, whereas, during the second quarter of 2016, the trial was in the later stages of follow-up.

Grant income for the six months ended June 30, 2016 and 2015 was approximately \$0.5 million and \$1.1 million, respectively. The decrease of approximately \$0.6 million in the first half of 2016 as compared to the first half of 2015 is due to the timing of activities associated with the DYNAMIC clinical trial. During the first half of 2015, the DYNAMIC clinical trial was actively enrolling patients, whereas, during the first half of 2016, the trial was in the later stages of follow-up.

*Collaboration Income.* As a result of the Janssen Agreement, collaboration income for each of the three month periods ended June 30, 2016 and 2015 was approximately \$0.9 million. A ratable portion of the payment to Capricor was recognized in both the three month periods ended June 30, 2016 and 2015 under the terms of the Janssen Agreement.

Collaboration income for the six months ended June 30, 2016 and 2015 was approximately \$1.8 million and \$2.0 million, respectively. A ratable portion of the payment to Capricor was recognized in both the six month periods ended June 30, 2016 and 2015 under the terms of the Janssen Agreement. We periodically review the estimated performance period of the Janssen Agreement based on the estimated progress of our project with Janssen.

*Interest Expense.* Interest expense for the three months ended June 30, 2016 and 2015 was \$76,887 and \$61,681, respectively. This slight increase in interest expense in the second quarter of 2016 as compared to the same period of 2015 is due to accrued interest on the CIRM loan award.

Interest expense for the six months ended June 30, 2016 and 2015 was \$143,011 and \$123,362, respectively. The slight increase in interest expense in the first half of 2016 as compared to the same period in 2015 is due to the outstanding principal balance of the CIRM loan award being higher in the first half of 2016 as compared to the same period of 2015.

## Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of June 30, 2016 and December 31, 2015 and our net increase (decrease) in cash and cash equivalents for the six months ended June 30, 2016 and 2015, and is intended to supplement the more detailed discussion that follows. The amounts stated in the tables below are expressed in thousands.

Liquidity and capital resources	June 30, 2016	December 31, 2015
Cash and cash equivalents	\$ 8,851	\$ 5,568
Working capital	\$ 5,604	\$ 7,461
Stockholders' equity (deficit)	\$ (5,116)	) \$ (1,032)

	Six months ended June 30,	
Cash flow data	2016	2015
Cash provided by (used in):		

Edgar Filing: CAPRICOR THERAPEUTICS, INC. - Form 10-Q

Operating activities	\$ (9,065 )	\$ (3,930 )
Investing activities	5,417	(15,548 )
Financing activities	6,931	16,481
Net increase (decrease) in cash and cash equivalents	\$ 3,283	\$ (2,997 )

Our total cash and cash equivalents as of June 30, 2016 were approximately \$8.9 million compared to approximately \$5.6 million as of December 31, 2015. The increase in cash and cash equivalents from December 31, 2015 to June 30, 2016 is primarily due to the approximately \$4.1 million received as a result of a registered direct offering of our common stock and a concurrent private placement of warrants to purchase shares of our common stock completed in the first quarter of 2016, along with an allocation of marketable securities to cash and cash equivalents. Furthermore, we received payments totaling \$3.0 million from CIRM in relation to loan award operational milestones that we reached in the first half of 2016. Total marketable securities, consisting primarily of United States treasuries, were approximately \$2.5 million as of June 30, 2016, as compared to \$8.0 million as of December 31, 2015. The decrease in working capital and stockholders' equity (deficit) as of June 30, 2016 as compared to December 31, 2015 is primarily due to operational expenditures coupled with the approximately \$4.1 million received in the first quarter of 2016 as a result of a registered direct offering of our common stock and a concurrent private placement of warrants to purchase shares of our common stock. As of June 30, 2016, we had approximately \$19.0 million in total liabilities, of which approximately \$2.7 million was recorded as deferred income under the Janssen Agreement. As of June 30, 2016, we had approximately \$5.6 million in net working capital. We incurred a net loss of approximately \$4.7 million for the three months ended June 30, 2016 compared to a net loss of approximately \$3.1 million in the same period of 2015 and we incurred a net loss of approximately \$9.0 million for the six months ended June 30, 2016 compared to a net loss of approximately \$6.6 million in the same period of 2016.

Cash used in operating activities was approximately \$9.1 million and \$3.9 million for the six months ended June 30, 2016 and 2015, respectively. The difference of approximately \$5.2 million in cash from operating activities is primarily due to an increase in net loss for the six months ended June 30, 2016 of approximately \$2.4 million as compared to the same period of 2015. Additionally, in the six months ended June 30, 2015, cash provided by the release of restricted cash totaled approximately \$2.4 million as compared to a net change of zero in restricted cash for the same period of 2016. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, including as we expand our technology portfolio, engage in further research and development activities and, in particular, conduct pre-clinical studies and clinical trials, we expect to continue incurring substantial and increasing losses, which will generate negative net cash flows from operating activities.



We had cash flow provided by investing activities of approximately \$5.4 million for the six months ended June 30, 2016 and cash used in investing activities of approximately \$15.5 million for the six months ended June 30, 2015. The increase in cash provided by investing activities for the six months ended June 30, 2016 as compared to the same period of 2015 is primarily due to the purchase of marketable securities in the first half of 2015 as compared to the redemption of marketable securities in the first half of 2016.

We had cash provided by financing activities of approximately \$6.9 million and \$16.5 million for the six months ended June 30, 2016 and 2015, respectively. The decrease in cash provided by financing activities for the six months ended June 30, 2016 as compared to the same period of 2015 is primarily the result of two private placements of our common stock that were completed during the first quarter of 2015, for which gross proceeds totaled approximately \$17.0 million, as compared to the approximately \$3.9 million in net proceeds received from a registered direct offering of our common stock and a concurrent private placement of warrants to purchase shares of our common stock that were completed during the first quarter of 2016. Furthermore, we received \$3.0 million in loan proceeds from our CIRM Loan Award in the first half of 2016.

Phase II of Capricor's ALLSTAR trial has been funded in large part through a loan award from CIRM. The Company and CIRM recently entered into an amendment to the CIRM Loan Amendment pursuant to which the parties agreed upon a schedule for future disbursements of the proceeds of the loan amount based upon the achievement of specified operational milestones. As a result of the CIRM Loan Amendment and because the Company is decreasing the number of patients to be enrolled in the ALLSTAR clinical trial, it is likely that the Company will not need to take down the full amount available for disbursement under the Loan Agreement with CIRM, or the CIRM Loan Agreement, and that certain of the operational milestones tied to patient enrollment will not be met. We believe that the amount that will ultimately be disbursed will be approximately 70-75% of the total amount specified in the CIRM Loan Agreement, thus reducing the total amount of debt incurred thereunder. The loss of funding under the CIRM Loan Agreement could cause delays under our ALLSTAR trial. Subject to sufficient funding, following completion of the Phase II trial, there may 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 is required to reimburse Janssen for its costs of development up to an agreed-upon maximum amount. If Janssen exercises its option under the Janssen Agreement to enter into an exclusive license agreement with Capricor, Janssen will be responsible for any additional trials and future development costs with respect to CAP-1002, except for certain excluded indications as may be determined.

Our Phase I/II HOPE-Duchenne trial of CAP-1002 in DMD-associated cardiomyopathy will be funded in part through a grant award from CIRM for approximately \$3.4 million, which was entered into in June 2016. In April 2015, the FDA granted orphan drug designation to CAP-1002 for the treatment of DMD. Orphan drug designation is granted by the FDA's Office of Orphan Drug Products to drugs intended to treat a rare disease or condition affecting fewer than 200,000 people in the U.S. This designation confers special incentives to the drug developer, including tax credits on the clinical development costs and prescription drug user fee waivers and may allow for a seven year period of market exclusivity in the U.S. upon FDA approval.

We will need substantial additional capital in order to continue the development of Cenderitide. In March 2015, we completed enrollment of a Phase II clinical trial of Cenderitide and decided to conduct an additional small study to further assess the safety and efficacy of this product candidate, which included higher dose levels of Cenderitide. The trial completed dosing of study participants in March 2016, and Capricor is determining the future strategy for the development of Cenderitide, which may include exploring potential out-licensing arrangements. In March 2011, the FDA granted fast track designation to Cenderitide in the post-acute period. According to the FDA's website, fast track designation facilitates the development and expeditious review of drugs and biologics intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

Our research and development expenses will continue to increase as we further develop our exosomes program and if we conduct additional studies with CAP-1002, such as a second part of the DYNAMIC study.

From inception through June 30, 2016, we financed our operations through private and public sales of our equity securities, NIH grants, a payment from Janssen, a CIRM loan and a CIRM grant award. In the first quarter of 2016, we completed a registered direct offering of our common stock and a concurrent private placement of warrants to purchase shares of our common stock, securing approximately \$4.1 million in additional capital through the issuance of securities. Furthermore, we received \$3.0 million in loan proceeds from our CIRM Loan Award in the first half of 2016. 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;
- the costs of manufacturing our product candidates;
- 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 2016 Financing.*** On March 14, 2016, we entered into a Subscription Agreement, or the Subscription Agreement, with certain investors, or the Investors, pursuant to which, on March 16, 2016, we issued and sold to the Investors an aggregate of approximately \$4.1 million of our registered and unregistered securities. On March 16, 2016, in accordance with the Subscription Agreement, we issued and sold to the Investors, and the Investors purchased from us, an aggregate of 1,692,151 shares, or the Shares, of our common stock at a purchase price of \$2.40 per Share, or the Public Offering. This offering included participation from the Company's officers and directors. The Shares were issued pursuant to our shelf registration statement on Form S-3 (File No. 333-207149), which was

initially filed with the Securities and Exchange Commission, or the SEC, on September 28, 2015 and declared effective by the SEC on October 26, 2015. A prospectus supplement relating to the Public Offering was filed with the SEC on March 15, 2016.

Pursuant to the Subscription Agreement, we also issued and sold to the Investors, in a concurrent private placement, or the Private Placement, and, together with the Public Offering, the Offerings, warrants to purchase up to an aggregate of 846,073 shares of our common stock, or the Warrants, and, together with the Shares, the Securities. Each Warrant has an exercise price of \$4.50 per share, will initially become exercisable on the date that is six months and one day from the date of issuance, and will expire on the date that is three years from the date of issuance.

We received net proceeds of approximately \$3.9 million from the sale of the Securities in the Offerings, after deducting the placement agent fees and estimated offering expenses payable by us.

In connection with the Private Placement, we entered into a Registration Rights Agreement with the Investors on March 14, 2016, pursuant to which we agreed to (i) prepare and file with the SEC a registration statement to register for resale the shares of common stock issuable upon exercise of the Warrants within 90 calendar days following the closing of the Private Placement, and (ii) use our reasonable efforts to cause such registration statement to be declared effective by the SEC as soon as practicable. In accordance with the terms of the Registration Rights Agreement, we registered for resale the shares of common stock issuable upon exercise of the Warrants pursuant to our registration statement on Form S-3 (File No. 333-212017), which was filed with the SEC on June 14, 2016 and declared effective by the SEC on June 30, 2016.

SC&H Capital, or the Placement Agent, served as our placement agent for the Offerings. In consideration for services rendered as the Placement Agent in the Offerings, we paid to the Placement Agent upon the closings of the Offerings a cash fee equal to approximately \$73,000, or 6.0% of the gross proceeds of the Shares sold to certain Investors identified by the Placement Agent. We also reimbursed the Placement Agent for its reasonable expenses actually and reasonably incurred in connection with its engagement, which such expenses did not exceed \$5,000, and paid the reasonable legal fees of the Placement Agent's counsel, which such expenses did not exceed \$10,000.

Certain of our officers and directors purchased Securities pursuant to the Offerings. Each of our officers and directors who purchased Warrants in the Private Placement paid a purchase price of \$0.125 per share of common stock issuable upon exercise of such Warrants upon the closing of the Private Placement.

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

In connection with PIPE 2, we entered into a Registration Rights Agreement with the investors in PIPE 2 on February 3, 2015. Pursuant to the terms of the Registration Rights Agreement for PIPE 2, we were obligated (i) to prepare and file with the SEC a registration statement to register for resale the shares issued and sold in PIPE 2, and (ii) to use our reasonable best efforts to cause the applicable registration statement to be declared effective by the SEC as soon as practicable, in each case subject to certain deadlines. We filed a Registration Statement on Form S-1 (SEC File No. 333-202589), or the PIPE Form S-1, to register for resale the shares of common stock underlying the shares issued in PIPE 2, which such PIPE Form S-1 was declared effective by the SEC on March 30, 2015. On June 4, 2015, we filed a post-effective amendment to the PIPE Form S-1 to convert the PIPE Form S-1 to a Registration Statement on Form S-3, which post-effective amendment was declared effective by the SEC on June 11, 2015.

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

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

In connection with PIPE 1, we also entered into a Registration Rights Agreement with the PIPE 1 investors on January 9, 2015. Pursuant to the terms of the Registration Rights Agreement, we were obligated (i) to prepare and file with the SEC a registration statement to register for resale the shares issued and sold in PIPE 1, and (ii) to use our reasonable best efforts to cause the applicable registration statement to be declared effective by the SEC as soon as practicable, in each case subject to certain deadlines. We filed the PIPE Form S-1 to register for resale the shares of common stock underlying the shares issued in PIPE 1, which such PIPE Form S-1 was declared effective by the SEC on March 30, 2015. On June 4, 2015, we filed a post-effective amendment to the PIPE Form S-1 to convert the PIPE Form S-1 to a Registration Statement on Form S-3, which post-effective amendment was declared effective by the SEC on June 11, 2015.

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

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

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

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

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

So long as Capricor is not in default under the terms of the CIRM Loan Agreement, the loan may be forgiven during the term of the project period if Capricor abandons the trial due to the occurrence of a no-go milestone. After the end of the project period, the loan may also be forgiven if Capricor elects to abandon the project under certain circumstances. Under the terms of the CIRM Loan Agreement, Capricor is required to meet certain financial milestones by demonstrating to CIRM prior to each disbursement of loan proceeds that it has sufficient funds available to cover all costs and expenses anticipated to be required to continue Phase II of the ALLSTAR trial for at least the following 12-month period, less the costs budgeted to be covered by planned loan disbursements. Capricor did not issue stock, warrants or other equity to CIRM in connection with this loan award. Additionally, on September 30, 2015, we entered into a Joinder Agreement with Capricor and CIRM, pursuant to which, among other things, we agreed to become a loan party under the CIRM Loan Agreement and to be jointly and severally responsible with Capricor for the performance of, and to be bound by the obligations and liabilities under, the CIRM Loan Agreement, subject to the rights and benefits afforded to a loan recipient thereunder. The balance of the loan with accrued interest is due in 2018, unless extended pursuant to the terms of the CIRM Loan Agreement.

In addition to the foregoing, 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.

### ***CIRM Grant Award***

On June 16, 2016, Capricor entered into a Grant Award with CIRM in the amount of approximately \$3.4 million to fund, in part, Capricor's Phase I/II HOPE-Duchenne clinical trial investigating CAP-1002 for the treatment of Duchenne muscular dystrophy-associated cardiomyopathy, or the CIRM Award. Pursuant to terms of the CIRM Award, the disbursements will be tied to the achievement of specified operational milestones. If CIRM determines, in its sole discretion, that Capricor has not complied with the terms and conditions of the CIRM Award, CIRM may suspend or permanently cease disbursements or pursue other remedies as allowed by law. In addition, the terms of the CIRM Award include a co-funding requirement pursuant to which Capricor is required to spend approximately \$2.3 million of its own capital to fund the HOPE-Duchenne clinical trial. If Capricor fails to satisfy its co-funding requirement, the amount of the CIRM Award may be proportionately reduced. The CIRM Award is further subject to

the conditions and requirements set forth the CIRM Grants Administration Policy for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, CCR Sections 100600-100612, and the sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from CIRM Funded Research as set forth in Title 17, CCR Section 100608. The maximum royalty on net commercial revenue that Capricor may be required to pay to CIRM is equal to nine times the total amount awarded and paid to Capricor.

After completing the CIRM funded research project and after the award period end date, estimated to be in late 2017 or in 2018, Capricor has the right to treat the CIRM Award as a loan, the terms of which will be determined based on various factors, including the stage of the research and the stage of development at the time the election is made. On June 20, 2016, Capricor entered into a Loan Election Agreement with CIRM whereby, among other things, CIRM and Capricor agreed that, if converted, the term of the loan would be five years from the date of execution of the applicable loan agreement; provided that the term of the loan will not exceed ten years from the date on which the CIRM Award was granted. Beginning on the date of the loan, the loan shall bear interest on the unpaid principal balance plus the interest that was accrued prior to the election point according to the terms set forth in CIRM's Loan Policy ("New Loan Balance") at a per annum rate equal to the LIBOR rate for a three-month deposit in U.S. dollars, as published by the Wall Street Journal on the loan date, plus one percent. Interest shall be compounded annually on the outstanding New Loan Balance commencing with the loan date and the interest shall be payable, together with the New Loan Balance, upon the due date of the loan. If Capricor elects to treat the CIRM Award as a loan, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements. Capricor will not make its decision as to whether it will elect to convert the CIRM Award into a loan until after the end of the HOPE-Duchenne trial. Since Capricor may be required to repay some or all of the amounts awarded by CIRM, the Company will account for this award as a liability rather than revenue. If Capricor were to lose this funding, it may be required to delay, postpone, or cancel its HOPE-Duchenne trial or otherwise reduce or curtail its operations, unless it was able to obtain adequate financing for its clinical trial from additional sources. In July 2016, Capricor received the first disbursement of \$2.0 million under the terms of the CIRM Award.



### ***NIH Grant Award***

In August 2013, Capricor was approved for a Phase IIB bridge grant through the NIH Small Business Innovation Research, or SBIR, program for continued development of its CAP-1002 product candidate. Under the terms of the grant, approximately \$2,879,437 will be disbursed to us over a period of approximately three years, subject to annual and quarterly reporting requirements. In June 2014, Capricor received approval from the NIH to deploy this grant to fund the first part of the DYNAMIC trial. The first part of the DYNAMIC trial used CAP-1002 to treat patients with advanced heart failure. As of June 30, 2016, the full award of \$2.9 million had been incurred under the terms of the NIH award.

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

There were no off-balance sheet arrangements as described by Item 303(a)(4) of Regulation S-K as of June 30, 2016.

### **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.

### ***CIRM Grant Award***

Capricor will account for the disbursements under its CIRM Award as long-term liabilities. Capricor will recognize the CIRM grant disbursements as a loan payable as the principal is disbursed rather than recognizing the full amount of the grant award. After completing the CIRM funded research project and after the award period end date, Capricor has the right to treat the CIRM Award as a loan, the terms of which will be determined based on various factors, including the stage of the research and the stage of development at the time the election is made. Since Capricor may be required to repay some or all of the amounts awarded by CIRM, the Company accounts for this award as a liability rather than income.

### ***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, or FASB, Accounting Standards Codification, or 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, or VSOE, of selling price, if it exists, or third-party evidence, or TPE, of selling price, if it exists. If neither VSOE nor TPE of selling price exists 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 Capricor's Collaboration Agreement with Janssen did not meet the criteria to be considered separate accounting units for the purposes of revenue recognition. As a result, we recognized revenue from non-refundable, upfront fees ratably over the term of our performance under the agreement. The upfront payments received, pending recognition as revenue, are recorded as deferred revenue and are classified as a short-term or long-term liability on the consolidated balance sheets and amortized over the estimated period of performance. We periodically review the estimated performance period of our contract based on the progress of our project.

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

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

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

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

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

### *Stock-Based Compensation*

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

We expense the fair value of stock-based compensation over the vesting period. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. This valuation model requires us to make assumptions and judgments about the variables used in the calculation. These variables and assumptions include the weighted-average period of time that the options granted are expected to be outstanding, the volatility of our common stock, the risk-free interest rate and the estimated rate of forfeitures of unvested stock options.

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

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

### ***Warrant Liability***

We previously accounted for warrants issued in connection with the financing we completed in April 2012 and the embedded derivative warrant liability contained in the secured convertible promissory notes we issued in March 2013, or the 2013 Notes, in accordance with the guidance on Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, which provides that we classify the warrant instrument as a liability at its fair value and adjust the instrument to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized as a component of other income or expense. The 2013 Notes converted into shares of Company common stock and additional warrants for Company common stock were issued to the holders. Management has determined the value of the warrant liability to be insignificant at June 30, 2016, and no such liability has been reflected on the consolidated balance sheet.

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

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

### ***Restricted Cash***

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

***Recently Issued or Newly Adopted Accounting Pronouncements***

In May 2014, the FASB issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers*, or 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 and replace it with a principle-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for reporting periods beginning after December 15, 2017, and early adoption is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. We have not yet selected a transition method nor have we determined the effect of the standard on our ongoing financial reporting.

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

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

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

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

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

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

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





**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 June 30, 2016, the fair value of our cash, cash equivalents, including restricted cash, and marketable securities was approximately \$11.4 million. Additionally, as of June 30, 2016, Capricor's portfolio was classified as cash, cash equivalents and marketable securities, which consisted primarily of money market funds and bank money market, which included short term United States treasuries, bank savings and checking accounts. Capricor did not have any investments with significant exposure to the subprime mortgage market issues.

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

**Item 4. Controls and Procedures.**

We have adopted and maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief 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 Chief 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 Chief 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 quarter ended June 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II — OTHER INFORMATION**

**Item 1. Legal Proceedings.**

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

**Item 1A. Risk Factors.**

There have been no material changes in our risk factors from those previously disclosed in Part 1, Item 1A, “Risk Factors,” of our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission on March 30, 2016.

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

Not applicable.

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

Not applicable.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

Agreement and Plan of Merger, dated as of August 15, 2007, by and among SMI Products, Inc., Nile Merger Sub, 2.1 Inc. and Nile Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on August 17, 2007).

Agreement and Plan of Merger and Reorganization, dated as of July 7, 2013, by and among Nile Therapeutics, 2.2 Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on July 9, 2013).

First Amendment to Agreement and Plan of Merger and Reorganization, dated as of September 27, 2013, by and 2.3 between Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on October 3, 2013).

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 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).

Form of Convertible Note Purchase Agreement entered into among the Company and various accredited investors 4.2 on March 15, 2013 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on March 22, 2013).

Form of Note issued to Various Accredited Investors on March 15, 2013 (includes Form of Warrant as Exhibit A) 4.3 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on March 22, 2013).

4.4 First Amendment to the Secured Convertible Promissory Notes (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on October 3, 2013).

4.5

Edgar Filing: CAPRICOR THERAPEUTICS, INC. - Form 10-Q

Registration Rights Agreement, dated as of March 14, 2016, by and among the Company and the Investors (incorporated by reference to Exhibit 4.1 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on March 16, 2016).

4.6 Form of Warrant, issued by the Company to the Investors on March 16, 2016 (incorporated by reference to Exhibit 4.2 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on March 16, 2016).

10.1 Amendment to Notice of Loan Award, dated as of May 12, 2016, by and between Capricor, Inc. and the California Institute for Regenerative Medicine.\*‡

10.2 Third Amendment to Lease, dated as of May 25, 2016, by and between Capricor, Inc. and The Bubble Real Estate Company, LLC, a California limited liability company.\*

10.3 Notice of Award, dated as of June 16, 2016, by and between Capricor, Inc. and the California Institute for Regenerative Medicine.\*‡

10.4 Loan Election Agreement, dated as of June 20, 2016, by and between Capricor, Inc. and the California Institute for Regenerative Medicine.\*

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 Chief 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.\*

32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

101 The following financial information from Capricor Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2016 formatted in eXtensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of June 30, 2016 and December 31, 2015, (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2016 and June 30, 2015, (iii) Condensed Consolidated Statement of Stockholders' Equity (Deficit) for the period from December 31, 2015 through June 30, 2016, (iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2016 and June 30, 2015, and (v) Notes to Condensed Consolidated Financial Statements.\*

\* Filed herewith.

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

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**CAPRICOR THERAPEUTICS,  
INC.**

Date: August 15, 2016 By: /s/ Linda Marbán, Ph.D.  
Linda Marbán, Ph.D.  
Chief Executive Officer  
(Principal Executive Officer)

Date: August 15, 2016 By: /s/ Leland Gershell, M.D., Ph.D.  
Leland Gershell, M.D., Ph.D.  
Chief Financial Officer  
(Principal Financial Officer)

## EXHIBIT INDEX

2.1 Agreement and Plan of Merger, dated as of August 15, 2007, by and among SMI Products, Inc., Nile Merger Sub, Nile Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on August 17, 2007).

2.2 Agreement and Plan of Merger and Reorganization, dated as of July 7, 2013, by and among Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on July 9, 2013).

2.3 First Amendment to Agreement and Plan of Merger and Reorganization, dated as of September 27, 2013, by and between Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on October 3, 2013).

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 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).

4.2 Form of Convertible Note Purchase Agreement entered into among the Company and various accredited investors on March 15, 2013 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on March 22, 2013).

4.3 Form of Note issued to Various Accredited Investors on March 15, 2013 (includes Form of Warrant as Exhibit A) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on March 22, 2013).

4.4 First Amendment to the Secured Convertible Promissory Notes (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on October 3, 2013).



Edgar Filing: CAPRICOR THERAPEUTICS, INC. - Form 10-Q

Registration Rights Agreement, dated as of March 14, 2016, by and among the Company and the Investors  
4.5 (incorporated by reference to Exhibit 4.1 to the Company's Amendment No. 1 to Current Report on Form 8-K/A,  
filed with the Commission on March 16, 2016).

Form of Warrant, issued by the Company to the Investors on March 16, 2016 (incorporated by reference to Exhibit  
4.6 4.2 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on March  
16, 2016).

10.1 Amendment to Notice of Loan Award, dated as of May 12, 2016, by and between Capricor, Inc. and the  
California Institute for Regenerative Medicine.\*‡

10.2 Third Amendment to Lease, dated as of May 25, 2016, by and between Capricor, Inc. and The Bubble Real Estate  
Company, LLC, a California limited liability company.\*

10.3 Notice of Award, dated as of June 16, 2016, by and between Capricor, Inc. and the California Institute for  
Regenerative Medicine.\*‡

10.4 Loan Election Agreement, dated as of June 20, 2016, by and between Capricor, Inc. and the California Institute  
for Regenerative Medicine.\*

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 Chief 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.\*

32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

The following financial information from Capricor Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2016 formatted in eXtensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of June 30, 2016 and December 31, 2015, (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2016 and March 31, 2015, (iii) Condensed Consolidated Statement of Stockholders' Equity (Deficit) for the period from December 31, 2015 through June 30, 2016, (iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2016 and June 30, 2015, and (v) Notes to Condensed Consolidated Financial Statements.\*

\* Filed herewith.

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