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, 2020

or

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

for the transition period from to

Commission File Number: 001-34058

CAPRICOR THERAPEUTICS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

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

8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211
(Address of principal executive offices including zip code)

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	CAPR	The Nasdaq Capital Market

As of August 7, 2020, there were 19,724,048 shares of the registrant's common stock, par value $0.001 per share, issued and outstanding.

INDEX TO QUARTERLY REPORT ON FORM 10-Q

	PAGES
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements	1
Condensed Consolidated Balance Sheets at June 30, 2020 (unaudited) and December 31, 2019	1
Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)	2
Condensed Consolidated Statements of Stockholders' Equity (unaudited)	3
Condensed Consolidated Statements of Cash Flows (unaudited)	4
Notes to Condensed Consolidated Financial Statements (unaudited)	5
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	25
Item 3. Quantitative and Qualitative Disclosures about Market Risk	41
Item 4. Controls and Procedures	42
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	43
Item 1A. Risk Factors	43
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	43
Item 3. Defaults Upon Senior Securities	43
Item 4. Mine Safety Disclosures	43
Item 5. Other Information	43
Item 6. Exhibits	44
Signatures	45

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," "contemplates," "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:

- how long we expect to maintain liquidity to fund our planned level of operations and our ability to obtain additional funds for our operations;
- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- the expectation, plans, projections, initiation, timing, progress and results of our research and development programs, preclinical studies, any clinical trials, compassionate uses, Investigational New Drug ("IND") filings, Clinical Trial Application ("CTA") filings, New Drug Application ("NDA") filings, and other regulatory submissions;
- regulatory developments involving products, including the ability to obtain regulatory approvals or otherwise bring products to market;
- the regulatory status of our drug candidates, including our ability to obtain and maintain orphan drug, rare pediatric and RMAT designations for our lead product candidate CAP-1002;
- 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 and retain commercial rights for our product candidates in the collaborations;
- 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;
- the implementation of our business model and strategic plans for our business, technologies and product candidates;
- our estimates of our expenses, ongoing losses, future revenue and capital requirements;
- the impact of taxes on our business;
- 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;
- the potential impact of COVID-19 on our business, including our ability to conduct clinical trials and further product candidate development;
- our ability to raise additional financing and the terms of any additional financing;
- 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 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, 2020 (unaudited)	December 31, 2019
CURRENT ASSETS		
Cash and cash equivalents	$ 36,252,623	$ 3,899,328
Marketable securities	-	5,986,050
Grant receivable	49,864	87,968
Prepaid expenses and other current assets	249,876	571,382
TOTAL CURRENT ASSETS	36,552,363	10,544,728
PROPERTY AND EQUIPMENT, net	486,815	442,806
OTHER ASSETS		
Intangible assets, net of accumulated amortization of $255,352 and $253,187, respectively	4,330	6,495
Other assets	82,446	119,608
TOTAL ASSETS	$ 37,125,954	$ 11,113,637
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 1,777,581	$ 897,992
Note payable, current	139,927	-
TOTAL CURRENT LIABILITIES	1,917,508	897,992
LONG-TERM LIABILITIES		
Note payable, net of current	178,233	-
CIRM liability	3,376,259	3,376,259
TOTAL LONG-TERM LIABILITIES	3,554,492	3,376,259
TOTAL LIABILITIES	5,472,000	4,274,251
COMMITMENTS AND CONTINGENCIES (NOTE 7)		
STOCKHOLDERS' EQUITY		
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, 19,697,576 and 5,227,398 shares issued and outstanding, respectively	19,698	5,227
Additional paid-in capital	111,583,959	81,215,647
Accumulated other comprehensive income (loss)	-	(757)
Accumulated deficit	(79,949,703)	(74,380,731)
TOTAL STOCKHOLDERS' EQUITY	31,653,954	6,839,386
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 37,125,954	$ 11,113,637

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,	
	2020	2019	2020	2019
REVENUE				
Revenue	$ 49,864	$ 410,353	$ 235,557	$ 640,857
TOTAL REVENUE	49,864	410,353	235,557	640,857
OPERATING EXPENSES				
Research and development	1,927,473	1,644,110	3,082,629	3,455,292
General and administrative	1,610,237	831,933	2,748,282	1,808,423
TOTAL OPERATING EXPENSES	3,537,710	2,476,043	5,830,911	5,263,715
LOSS FROM OPERATIONS	(3,487,846)	(2,065,690)	(5,595,354)	(4,622,858)
OTHER INCOME (EXPENSE)				
Investment income	3,692	21,956	26,382	59,779
Loss on disposal of fixed asset	-	(2,720)	-	(2,720)
TOTAL OTHER INCOME (EXPENSE)	3,692	19,236	26,382	57,059
NET LOSS	(3,484,154)	(2,046,454)	(5,568,972)	(4,565,799)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	-	-	757	(12,393)
COMPREHENSIVE LOSS	$ (3,484,154)	$ (2,046,454)	$ (5,568,215)	$ (4,578,192)
Net loss per share, basic and diluted	$ (0.23)	$ (0.59)	$ (0.51)	$ (1.35)
Weighted average number of shares, basic and diluted	15,130,685	3,457,833	11,004,733	3,374,557

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	For the Six Months Ended June 30, 2020					
	COMMON STOCK					
	SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME (LOSS)	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
Balance at December 31, 2019	5,227,398	$ 5,227	$ 81,215,647	$ (757)	$ (74,380,731)	$ 6,839,386
Issuance of common stock, net of fees	444,500	446	4,459,764	-	-	4,460,210
Exercise of pre-funded common stock warrants	3,158,304	3,158	-	-	-	3,158
Exercise of common warrants	78,304	78	86,056	-	-	86,134
Issuance of shares in abeyance	280,000	280	(280)	-	-	-
Stock-based compensation	-	-	287,807	-	-	287,807
Unrealized gain on marketable securities	-	-	-	757	-	757
Net loss	-	-	-	-	(2,084,818)	$ (2,084,818)
Balance at March 31, 2020	9,188,506	$ 9,189	$ 86,048,994	$ -	$ (76,465,549)	$ 9,592,634
Issuance of common stock, net of fees	3,059,959	3,060	19,492,179	-	-	19,495,239
Exercise of common warrants	4,172,390	4,172	5,340,016	-	-	5,344,188
Issuance of shares in abeyance	3,275,500	3,276	(3,276)	-	-	-
Stock-based compensation	-	-	704,350	-	-	704,350
Stock options exercised	1,221	1	1,696	-	-	1,697
Net loss	-	-	-	-	(3,484,154)	$ (3,484,154)
Balance at June 30, 2020	19,697,576	$ 19,698	$ 111,583,959	$ -	$ (79,949,703)	$ 31,653,954

	For the Six Months Ended June 30, 2019					
	COMMON STOCK					
	SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME (LOSS)	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
Balance at December 31, 2018	3,138,748	$ 3,138	$ 71,338,970	$ 12,393	$ (66,738,914)	$ 4,615,587
Issuance of common stock, net of fees	227,357	228	1,433,059	-	-	1,433,287
Stock-based compensation	-	-	223,166	-	-	223,166
Unrealized loss on marketable securities	-	-	-	(12,393)	-	(12,393)
Net loss	-	-	-	-	(2,519,345)	(2,519,345)
Balance at March 31, 2019	3,366,105	$ 3,366	$ 72,995,195	$ -	$ (69,258,259)	$ 3,740,302
Issuance of common stock, net of fees	100,553	100	543,039	-	-	543,139
Stock-based compensation	-	-	124,217	-	-	124,217
Fractional shares eliminated pursuant to reverse stock split	(27)	-	(193)	-	-	(193)
Stock options exercised	828	1	2,771	-	-	2,772
Net loss	-	-	-	-	(2,046,454)	(2,046,454)
Balance at June 30, 2019	3,467,459	$ 3,467	$ 73,665,029	$ -	$ (71,304,713)	$ 2,363,783

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,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (5,568,972)	$ (4,565,799)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed asset	-	2,720
Depreciation and amortization	65,614	86,401
Stock-based compensation	992,157	347,383
Change in assets - (increase) decrease:		
Receivables	38,104	60,781
Prepaid expenses and other current assets	321,506	348,765
Other assets	37,162	23,073
Change in liabilities - increase (decrease):		
Accounts payable and accrued expenses	879,589	311,583
NET CASH USED IN OPERATING ACTIVITIES	(3,234,840)	(3,385,093)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(6,130,193)	(15,243)
Proceeds from sales and maturities of marketable securities	12,117,000	3,000,000
Purchases of property and equipment	(107,458)	-
NET CASH PROVIDED BY INVESTING ACTIVITIES	5,879,349	2,984,757
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	23,955,449	1,976,426
Proceeds from note payable	318,160	-
Proceeds from exercise of pre-funded common stock warrants and warrants	5,433,480	-
Repurchase of fractional shares pursuant to reverse stock split	-	(193)
Proceeds from stock options	1,697	2,772
NET CASH PROVIDED BY FINANCING ACTIVITIES	29,708,786	1,979,005
NET INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	32,353,295	1,578,669
Cash, cash equivalents, and restricted cash balance at beginning of period	3,899,328	4,545,097
Cash, cash equivalents, and restricted cash balance at end of period	$ 36,252,623	$ 6,123,766
SUPPLEMENTAL DISCLOSURES:		
Interest paid in cash	$ -	$ -
Income taxes paid in cash	$ -	$ -

See accompanying notes to the unaudited condensed consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Capricor Therapeutics, Inc., a Delaware corporation (referred to herein as "Capricor Therapeutics" or the "Company"), is a clinical-stage biotechnology company focused on the discovery, development and commercialization of innovative cell and exosome-based therapies for the treatment and prevention of diseases. Capricor, Inc. ("Capricor"), a wholly-owned subsidiary of Capricor Therapeutics, 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, has two active 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 (the "SEC") on March 27, 2020, from which the December 31, 2019 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, 2020.

Certain reclassification of prior period amounts has been made to conform to the current year presentation.

Basis of Consolidation

Our condensed consolidated financial statements include the accounts of the Company and our 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 and a grant from the California Institute for Regenerative Medicine ("CIRM").

Cash, cash equivalents and marketable securities as of June 30, 2020 were approximately $36.3 million, compared to approximately $9.9 million as of December 31, 2019. The Company has entered into various Common Stock Sales Agreements with H.C. Wainwright & Co. LLC ("Wainwright") to create at-the-market equity programs under which the Company from time to time offered and sold shares of its common stock, par value $0.001 per share (see Note 3 – "Stockholders' Equity"). In March 2020, the Company entered into a warrant inducement transaction whereby an existing warrant holder exercised all existing warrants for gross proceeds of approximately $4.9 million (see Note 3 – "Stockholder's Equity").

Additionally, the Company has been awarded various grant and loan awards, which fund, in part, various pre-clinical and clinical activities (see Note 6 – "Government Grant Awards"). As of June 30, 2020, the Company has approximately $0.1 million remaining available under its grants and awards for disbursement, pursuant to the terms of the awards.

The Company's principal uses of cash are for research and development expenses, general and administrative expenses, capital expenditures and other working capital requirements.

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 its clinical trials and pre-clinical studies;
- the timing and costs associated with the manufacturing of its product candidates;
- the timing and costs associated with commercialization of its product candidates;
- 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 options for raising additional capital include potentially seeking 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 other assets, and from government grants.

The Company will require substantial additional capital to fund its operations, in particular if it elects to expand its clinical programs as contemplated by its current business plan. 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. 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. The Company would likely need to delay, curtail or terminate all or portions of its clinical trial programs. To the extent the Company issues additional equity securities, its existing stockholders would experience substantial dilution.

Reverse Stock Split

On June 4, 2019, the Company effected a reverse stock split of its outstanding shares of common stock at a ratio of one-for-ten pursuant to a Certificate of Amendment to the Company's Certificate of Incorporation filed with the Secretary of State of the State of Delaware. The reverse stock split was reflected on the Nasdaq Capital Market ("Nasdaq") beginning with the opening of trading on June 5, 2019. The primary purpose of the reverse stock split, which was approved by the Company's stockholders at the Company's annual stockholders meeting on May 29, 2019, was to enable the Company to regain compliance with the $1.00 minimum bid price requirement for continued listing on Nasdaq. Pursuant to the reverse stock split, every ten shares of the Company's issued and outstanding shares of common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value per share of the common stock. Unless otherwise indicated, all share and per share amounts of the common stock included in the accompanying condensed consolidated financial statements have been retrospectively adjusted to give effect to the reverse stock split for all periods presented, including reclassifying an amount equal to the reduction in par value to additional paid-in capital. Amounts of common stock resulting from the reverse stock split were rounded down to the nearest whole share and any resulting fractional shares were cancelled for cash. The number of authorized shares of the Company's common stock remained unchanged. The reverse stock split affected all issued and outstanding shares of the Company's common stock, and the respective numbers of shares of common stock underlying outstanding stock options, outstanding warrants and the Company's equity incentive plans were proportionately adjusted.

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 recoverability and fair value of intangible assets 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, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments with a maturity of less than 30 days at the date of purchase to be cash equivalents.

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

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets that total the same such amounts shown in the condensed consolidated statements of cash flows.

	June 30, 2020	June 30, 2019
Cash and cash equivalents	$ 36,252,623	$ 5,890,963
Restricted cash	-	232,803
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	$ 36,252,623	$ 6,123,766

For the six months ended June 30, 2019, the Company had an outstanding letter of credit for $232,803 as a security deposit for its operating lease agreement for corporate office space (see Note 7 – "Commitments and Contingencies"). The Company was required to maintain this deposit for the duration of the lease agreement. The letter of credit was cancelled in December 2019. The Company had no restricted funds as of June 30, 2020.

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 (loss) 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 $63,449 and $64,763 for the six months ended June 30, 2020 and 2019, respectively.

Property and equipment, net consisted of the following:

	June 30, 2020	December 31, 2019
Furniture and fixtures	$ 43,617	$ 43,617
Laboratory equipment	1,038,624	931,166
Leasehold improvements	47,043	47,043
	1,129,284	1,021,826
Less accumulated depreciation	(642,469)	(579,020)
Property and equipment, net	$ 486,815	$ 442,806

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

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. Certain 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. Total amortization expense was $2,165 and $21,638 for the six months ended June 30, 2020 and 2019, respectively. A summary of future amortization expense as of June 30, 2020 is as follows:

Years ended	Amortization Expense
2020 (6 months)	2,165
2021	2,165

The Company reviews goodwill and intangible assets at least annually for possible impairment. Goodwill and 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. No impairment was recorded for the six months ended June 30, 2020 and 2019.

Leases

Effective January 1, 2019, the Company adopted ASC Topic 842, "Leases" ("ASC 842"), using the optional transition method utilizing the effective date as its date of initial application, for which prior periods are presented in accordance with the previous guidance in ASC Topic 840, "Leases" ("ASC 840").

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than 12 months are recognized on the balance sheet as right of use assets and short-term and long-term lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. The Company monitors its plans to renew its leases no less than on a quarterly basis. In addition, the Company's lease agreements generally do not contain any residual value guarantees or restrictive covenants.

Operating lease liabilities and their corresponding right of use assets are recorded based on the present value of future lease payments over the expected remaining lease term at lease commencement. Lease cost for operating leases is recognized on a straight-line basis over the lease term as an operating expense. Certain adjustments to the right of use asset may be required for items such as lease prepayments or incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rate.

In accordance with ASC 842, components of a lease should be bifurcated between lease components and non-lease components. The fixed and in-substance fixed contract consideration identified must then be allocated based on the respective relative fair values to the lease components and non-lease components. However, ASC 842 provides a practical expedient that allows an accounting policy election to not separate lease and non-lease components by class of underlying asset. In using this expedient, the lease component and non-lease components are accounted for together as a single component. For real estate leases, the Company has elected to account for the lease and non-lease components together for existing classes of underlying assets and allocates the contract consideration to the lease component only. This practical expedient is not elected for manufacturing facilities and equipment embedded in product supply arrangements.

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

Revenue Recognition

For contracts completed as of December 31, 2017, revenue was recognized in accordance with ASC 605 and other superseded standards. The company applied ASU 606 using the modified retrospective approach for all contracts in process as of January 1, 2018.

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. Because the terms of the CIRM Award allow Capricor to elect to convert the grant into a loan after the end of the project period, the CIRM Award is being classified as a liability rather than income (see Note 6 - "Government Grant Awards"). Grant income is due upon submission of reimbursement request. The transaction price varies for grant income based on the expenses incurred under the awards.

Miscellaneous Income

Revenue is recognized in connection with the delivery of doses which were developed as part of our past R&D efforts. Income is recorded when the Company has satisfied the obligations as identified in the contracts with the customer (see Note 9 – "Related Party Transactions"). Miscellaneous income is due upon billing. Miscellaneous income is based on contracts with fixed transaction prices.

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 under accounts payable and accrued expenses. 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 Financial Accounting Standards Board ("FASB") ASC 730-10, *Research and Development*. Research and development costs amounted to approximately $1.9 million and $1.6 million for the three months ended June 30, 2020 and 2019, respectively, and approximately $3.1 million and $3.5 million for the six months ended June 30, 2020 and 2019, respectively.

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders' equity during the period except those resulting from investments by, or distributions to, stockholders. The Company's comprehensive loss was approximately $3.5 million and $2.0 million for the three months ended June 30, 2020 and 2019, respectively, and approximately $5.6 million and $4.6 million for the six months ended June 30, 2020 and 2019, respectively. The Company's other comprehensive income (loss) is related to a net unrealized gain (loss) on marketable securities. For both the three months ended June 30, 2020 and 2019, the Company's other comprehensive income (loss) was zero. For the six months ended June 30, 2020 and 2019, the Company's other comprehensive income (loss) was $757 and $(12,393), respectively.

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

Clinical Trial Expense

As part of the process of preparing our condensed consolidated financial statements, we are required to estimate our accrued expenses. Our clinical trial accrual process is designed to account for expenses resulting from our obligations under contracts with vendors, consultants, and contract research organizations ("CROs"), and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by matching the appropriate expenses with the period in which services are provided and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models that take into account discussion with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on the facts and circumstances known to us at that time. Our clinical trial accrual and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period.

Business Uncertainty Related to the Coronavirus

As a result of the spread of the COVID-19 coronavirus, uncertainties have arisen that could potentially impact enrollment of and the ability to conduct clinical trials, deliverables related to contract performance, payments from trial sponsors including Cedars-Sinai Medical Center, as we describe further below, workforce stability, supply chain disruptions or delays, timing of grant disbursements as well as other potential business operations. While the disruption is currently expected to be temporary, there is considerable uncertainty around its expected duration and as a result, the Company is considering the impact of COVID-19 on its ability to conduct both pre-clinical development and clinical studies. In addition to potential impact on grant disbursements, there may be risks to the Company's ability to obtain financing from other sources due to the impact of the coronavirus. There could be other financial impacts on our business due to the coronavirus, the specifics of which are unknown at this time.

In light of the increased uncertainties due to COVID-19 and its economic and other impacts and to uncertainties around the timing and availability of grant disbursements, the loss of revenue from the delay and/or suspension of the REGRESS and ALPHA trials as well as any potential equity and debt financings, the Company applied for a loan under the Small Business Administration (the "SBA") Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Security Act of 2020 (the "CARES Act"). On April 29, 2020, the Company was approved and received a loan of $318,160 (the "Loan") under the SBA Paycheck Protection Program of the CARES Act. The Company utilized the funds for covered payroll costs and rent, all which the Company believes were in accordance with the relevant terms and conditions of the CARES Act (see Note 2 – "Note Payable").

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. For employees and directors, the expected life was calculated based on the simplified method as described by the SEC Staff Accounting Bulletin No. 110, Share-Based Payment. For other service providers, the expected life was calculated using the contractual term of the award. The Company's estimate of expected volatility was based on the historical stock price of the Company. 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.

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

Basic and Diluted Loss per Share

The Company reports earnings per share in accordance with FSAB ASC 260-10,*Earnings per Share.* Basic earnings (loss) per share is computed by dividing income (loss) available to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is computed similarly to basic earnings (loss) per share except that the denominator is increased to include the number of additional shares of common stock that would have been outstanding if the potential shares of common stock had been issued and if the additional shares of common stock were dilutive.

For the three and six months ended June 30, 2020 and 2019, warrants and options to purchase 2,607,117 and 638,849 shares of common stock, respectively, have been excluded from the computation of potentially dilutive securities. Potentially dilutive common shares, which primarily consist of stock options issued to employees, consultants, and directors as well as warrants issued, have been excluded from the diluted loss per share calculation because their effect is anti-dilutive. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between basic and diluted loss per share for the three and six months ended June 30, 2020 and 2019.

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 tables summarize the fair value measurements by level for assets and liabilities measured at fair value on a recurring basis:

	December 31, 2019			
	Level I	Level II	Level III	Total
Marketable Securities	$ 5,986,050	$ -	$ -	$ 5,986,050

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 from its carrying amount because the stated rates for such debt reflect current market rates and conditions.

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

Recent Accounting Pronouncements

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808):* clarifying the interaction between Topic 808 and Topic 606. The amendments in the update clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account; adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 when an entity is assessing whether the collaborative arrangement or a party to the arrangement is within the scope of Topic 606; requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The amendments for this update are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company adopted ASU 2018-18 and all subsequent updates related to this topic in the first quarter of 2020. The adoption of this update did not have a material impact on the Company's financial statements.

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 consolidated financial statement presentation or disclosures.

2. NOTE PAYABLE

Paycheck Protection Program Loan

On April 7, 2020, Capricor applied to City National Bank ("CNB") under the SBA Paycheck Protection Program of the CARES Act for the Loan in the amount of $318,160. On April 29, 2020, the Loan was approved and Capricor received the Loan proceeds, which we used for covered payroll costs, rent and utilities in accordance with the relevant terms and conditions of the CARES Act.

The Loan, which took the form of a promissory note issued by Capricor (the "Promissory Note"), has a two-year term, matures on April 29, 2022, and bears interest at a rate of 1.0% per annum. Monthly principal and interest payments, less the amount of any potential forgiveness, will commence on November 29, 2020. Capricor did not provide any collateral or guarantees for the Loan, nor did Capricor pay any facility charge to obtain the Loan. The Promissory Note provides for customary events of default, including, among others, those relating to failure to make payment, bankruptcy, breaches of representations and material adverse events. Capricor may prepay the principal of the Loan at any time without incurring any prepayment charges.

The Loan may be forgiven partially or fully if the Loan proceeds are used for eligible purposes, including payroll costs, rent and utilities, provided that such amounts are incurred during an 8 or 24-week period that commenced on April 29, 2020. Any forgiveness of the Loan will be subject to approval by the SBA and CNB and will require Capricor to apply for such treatment in the future. While the Company currently believes that its use of the loan proceeds will meet the conditions for forgiveness of the Loan, it cannot be sure that it will be eligible for forgiveness, in whole or in part.

3. STOCKHOLDER'S EQUITY

Common Stock Sales Agreements

Since July 2019, the Company has entered into multiple Common Stock Sales Agreements with Wainwright establishing "at-the-market", or ATM, programs by which Wainwright sold and may continue to sell common stock at the market prices prevailing at the time of sale. Wainwright is entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold plus reimbursement of certain expenses. These programs are referred to below as the "July 2019 ATM Program," the "August 2019 ATM Program," and the "May 2020 ATM Program" based on when each program was initiated. In addition, the Company completed a public offering of its common stock in December 2019 and a warrant inducement offer in March 2020.

3. STOCKHOLDER'S EQUITY (Continued)

July 2019 ATM Program

From July 22, 2019 through expiration of the July 2019 ATM Program on August 23, 2019, the Company sold an aggregate of 418,450 shares of common stock under the July 2019 ATM Program at an average price of approximately $4.30 per share for gross proceeds of approximately $1.8 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of Wainwright and legal fees in the aggregate amount of approximately $0.1 million.

August 2019 ATM Program

On August 29, 2019, the Company initiated the August 2019 ATM Program. Since August 29, 2019 and through May 4, 2020, the Company sold an aggregate of 360,316 shares of common stock under the August 2019 ATM Program at an average price of approximately $3.07 per share for gross proceeds of approximately $1.1 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of Wainwright and legal fees in the aggregate amount of approximately $0.1 million. As of May 4, 2020, the August 2019 ATM Program has expired and been replaced with the May 2020 ATM Program described below.

May 2020 ATM Program

On May 4, 2020, the Company initiated the May 2020 ATM Program. The Company filed the May 2020 ATM with an aggregate offering price of up to $40.0 million. Since May 4, 2020 and through the date of this filing, the Company has sold an aggregate of 3,059,959 shares of common stock under the May 2020 ATM Program at an average price of approximately $6.59 per share for gross proceeds of approximately $20.2 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of Wainwright and legal fees in the aggregate amount of approximately $0.7 million.

December 2019 Financing

In December 2019, the Company completed a public offering pursuant to which the Company issued (i) 531,173 shares of its common stock, (ii) warrants (the "December 2019 Common Warrants") to purchase up to 4,139,477 shares of common stock, and (iii) pre-funded warrants to purchase up to 3,608,304 shares of common stock, at a combined purchase price of $1.226 per share and associated common warrant and $1.225 per pre-funded warrant and associated common warrant, for an aggregate purchase price of approximately $5.1 million. The Company issued (a) to each purchaser of shares in the offering a common warrant to purchase a number of shares of common stock equal to the number of shares purchased by such purchaser in the offering, and (b) to each purchaser of pre-funded warrants in the offering a common warrant to purchase a number of shares of common stock equal to the number of pre-funded warrant shares underlying the pre-funded warrants purchased by such purchaser in the offering. In connection with the offering, the Company issued to designees of Wainwright, the placement agent for the offering, warrants (the "December 2019 Placement Agent Warrants") to purchase an aggregate of 203,915 shares of common stock. The December 2019 Placement Agent Warrants have an exercise price of $1.5325 per share, are immediately exercisable and expire in December 2024. Fees paid in conjunction with the deal, which included placement agent commissions, management fees, legal costs, and other offering expenses, amount to approximately $0.7 million in the aggregate and were recorded as a reduction to additional paid-in capital, resulting in net proceeds of approximately $4.4 million. As of March 25, 2020, prior to the March 2020 warrant inducement described below, 78,304 common warrants and all 3,608,304 pre-funded warrants had been exercised.

March 2020 Warrant Inducement

On March 25, 2020, the Company entered into a letter agreement (the "Exercise Agreement") with a holder of December 2019 Common Warrants (the "Exercising Holder"). Pursuant to the Exercise Agreement, in connection with exercise by the Exercising Holder of the remaining 4,000,000 December 2019 Common Warrants held by the Exercising Holder which had not been previously exercised, the Company agreed to issue 4,000,000 additional warrants (the "New Warrants") to purchase Common Stock. The December 2019 Common Warrants had a per share exercise price of $1.10, and pursuant to the Exercise Agreement, the Exercising Holder agreed to pay $1.225 per share to cover both the exercise price of the December 2019 Common Warrants and a $0.125 per share purchase price for the New Warrants. The New Warrants have an exercise price of $1.27 per share. A total of 724,500 shares were issued to the Exercising Holder, with the remaining 3,275,500 shares being held in abeyance until such time as it would not result in the Exercising Holder exceeding its beneficial ownership limitation of 4.99% of the Company's outstanding common stock. In the second quarter of 2020, the Company issued all shares that were being held in abeyance.

3. STOCKHOLDER'S EQUITY (Continued)

The New Warrants and the shares of Common Stock issuable upon the exercise of the New Warrants were not registered under the Securities Act of 1933, as amended (the "Securities Act"), and were offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act or Rule 506(b) promulgated thereunder. The New Warrants are exercisable immediately upon issuance, and have a term of exercise of 5 1/2 years.

The exercise of December 2019 Common Warrants by the Exercising Holder generated gross proceeds of approximately $4.9 million. Fees paid in conjunction with the Exercise Agreement, which included placement agent commissions, legal costs, and other offering expenses, amount to approximately $0.4 million. In connection with the Exercise Agreement, certain employees of the placement agent were issued new warrants (the "March 2020 Placement Agent Warrants") to purchase an aggregate of 200,000 shares of common stock. The March 2020 Placement Agent Warrants have an exercise price of $1.5313 per share and expire in March 2025. The holders of each of the New Warrants and of the March 2020 Placement Agent Warrants have the option to make a cashless exercise of such warrant if no resale registration statement covering the shares of the Company's Common Stock underlying such warrant is effective after six months. On May 7, 2020, the Company filed a resale registration statement on Form S-3 for the shares underlying the New Warrants and March 2020 Placement Agent Warrants, and that resale registration statement was declared effective by the SEC on May 19, 2020.

Outstanding Shares

At June 30, 2020, the Company had 19,697,576 shares of common stock issued and outstanding.

4. STOCK AWARDS, WARRANTS AND OPTIONS

Warrants

The following table summarizes all warrant activity for the six months ended June 30, 2020:

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2019	7,501,696	$ 0.65
Granted	4,200,000	1.28
Exercised	(11,408,998)	0.86
Outstanding at June 30, 2020	292,698	$ 1.44

4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

The following table summarizes all outstanding warrants to purchase shares of the Company's common stock:

		Warrants Outstanding			
Type	Grant Date	June 30, 2020	December 31, 2019	Exercise Price per Share	Expiration Date
Common Warrants	12/19/2019	61,173	4,139,477	$ 1.10	12/19/2024
Common Warrants	12/19/2019	31,525	203,915	$ 1.5325	12/17/2024
Pre-Funded Warrants	12/19/2019	-	3,158,304	$ 0.001	N/A
Common Warrants	3/27/2020	200,000	-	$ 1.5313	3/27/2025
		292,698	**7,501,696**		

Stock Options

The Company's Board of Directors (the "Board") has approved four stock option plans: (i) the 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan (which superseded the 2006 Stock Option Plan) (the "2012 Plan"), (iii) the 2012 Non-Employee Director Stock Option Plan (the "2012 Non-Employee Director Plan"), and (iv) the 2020 Equity Incentive Plan (the "2020 Plan").

At the time the merger between Capricor and Nile became effective, 414,971 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 414,971 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). For the fiscal years beginning on January 1, 2020 and 2019, the number of shares added was equal to 104,547 and 62,775 shares, respectively.

At the time the merger between Capricor and Nile became effective, 269,731 shares of common stock were reserved under the 2012 Non-Employee Director Plan for the issuance of stock options to members of the Board who are not employees of the Company.

On June 5, 2020, at the Company's annual stockholder meeting, the stockholders approved the 2020 Plan with 2,500,000 shares of common stock reserved under the 2020 Plan for the issuance of stock awards. The number of Shares available for issuance under the 2020 Plan shall be automatically increased on January 1 of each year, commencing with January 1, 2021, by an amount equal to the lesser of (i) four percent (4%) of the outstanding shares of Common Stock as of the last day of the immediately preceding fiscal year or (ii) such number of shares of Common Stock determined by the Compensation Committee in its sole discretion.

Each of the Company's stock option plans are administered by the Board, or the compensation committee of 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.

4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

The estimated weighted average fair value of the options granted during the three and six months ended June 30, 2020 were approximately $3.92 and $3.75 per share, respectively. No options were granted during the three and six months ended June 30, 2019.

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 in the six months ended June 30, 2020 as no options were issued during the six months ended June 30, 2019:

	June 30, 2020
Expected volatility	104% - 123%
Expected term	5 - 6 years
Dividend yield	0%
Risk-free interest rates	0.4 – 1.5%

Employee and non-employee stock-based compensation expense was as follows:

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
General and administrative	$ 621,830	$ 75,379	$ 869,327	$ 252,890
Research and development	82,520	48,838	122,830	94,493
Total	$ 704,350	$ 124,217	$ 992,157	$ 347,383

The Company does not recognize an income tax benefit as the Company believes that an actual income tax benefit may not be realized. For non-qualified stock options, the loss creates a timing difference, resulting in a deferred tax asset, which is fully reserved by a valuation allowance.

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. The fair value of stock options is determined using the Black-Scholes option-pricing model. The Company calculates the fair value for non-qualified options as of the date of grant and expenses over the applicable vesting periods. We account for forfeitures upon occurrence.

On February 12, 2020, pursuant to the authority granted to it under the 2012 Restated Equity Incentive Plan and the 2012 Non-Employee Director Stock Option Plan, the board of directors of the Company approved a program under which outstanding options and other awards granted under the 2012 Plan and the 2012 Director Plan to employees, officers and directors and designated service providers of the Company were repriced to their then current fair market value. There were 662,968 outstanding options which were repriced to $1.39 per share, which was the market price of our common stock on the date of the approval of the repricing. The effect of the modification generated a total incremental cost of approximately $178,000, of which approximately $171,000 was recognized in the first quarter of 2020 stock-based compensation expense with the remainder to be expensed over the remaining unvested period terms.

4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

The following is a schedule summarizing employee and non-employee stock option activity for the six months ended June 30, 2020:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at January 1, 2020	754,913	$ 12.63	$ -
Granted	1,587,058	1.49	
Exercised	(1,221)	1.39	$ 4,371
Expired/Cancelled	(26,331)	24.92	
Outstanding at June 30, 2020	2,314,419	$ 1.53	$ 7,127,763
Exercisable at June 30, 2020	757,780	$ 1.58	$ 2,296,390

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.

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, 2020, the Company maintained approximately $35.8 million of uninsured deposits.

6. GOVERNMENT GRANT AWARDS

CIRM Grant Award (HOPE)

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 were tied to the achievement of specified operational milestones. In addition, the terms of the CIRM Award included a co-funding requirement pursuant to which Capricor was required to spend approximately $2.3 million of its own capital to fund the CIRM funded research project. 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, California Code of Regulations (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 the 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.

6. GOVERNMENT GRANT AWARDS (Continued)

After completing the CIRM funded research project and at any time after the award period end date (but no later than the ten-year anniversary of the date of the award), Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and development of the program 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 Capricor elects to convert the grant into a loan, the term of the loan could be up to five years from the date of execution of the applicable loan agreement; provided that the maturity date of the loan will not surpass the ten-year anniversary of the grant date of the CIRM Award. Beginning on the date of the loan, the loan shall bear interest on the unpaid principal balance, plus the interest that has accrued prior to the election point according to the terms set forth in CIRM's Loan Policy (the "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 convert the CIRM Award into a loan, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements. Capricor has not yet made its decision as to whether it will elect to convert the CIRM Award into a loan. If we elect to do so, Capricor would be required to repay some or all of the amounts awarded by CIRM; therefore, the Company accounts for this award as a liability rather than income.

In June 2019, Capricor completed all milestones associated with the CIRM Award and expended all funds received. In the third quarter of 2019, Capricor completed all final close-out documentation associated with this award. As of June 30, 2020, Capricor's liability balance for the CIRM Award was approximately $3.4 million.

U.S. Department of Defense Grant Award

In September 2016, Capricor was approved for a grant award from the Department of Defense in the amount of approximately $2.4 million to be used toward developing a scalable, commercially-ready process to manufacture CAP-2003. Under the terms of the award, disbursements will be made to Capricor over a period of approximately three years, subject to annual and quarterly reporting requirements. The Company was granted a no-cost extension until September 29, 2020 to be able to utilize these funds. As of June 30, 2020, approximately $2.3 million has been incurred under the terms of the award.

7. COMMITMENTS AND CONTINGENCIES

Leases

Capricor leases space for its corporate offices from The Bubble Real Estate Company, LLC ("Bubble Real Estate") 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. Capricor subsequently entered into several amendments extending the term of the lease and modifying its terms. On January 11, 2019, Capricor entered into a Fourth Amendment to Lease (the "Fourth Lease Amendment") with the Bubble Real Estate. Under the terms of the Fourth Lease Amendment, the lease term extension commenced on January 1, 2019 and ended on December 31, 2019 with a base rent of $25,867 per month. The Company delivered to the landlord a letter of credit in the amount of $232,803 to cover payments of rent for the remainder of the 2019 lease term, which was subsequently cancelled, with the funds being returned to Capricor. Effective January 1, 2020, the Company entered into a Fifth Amendment to Lease with the Bubble Real Estate pursuant to which we extended our lease for an additional year ending December 31, 2020 and reduced the square footage of the leased premises. The monthly rental payment is $16,229 for this annual period.

7. COMMITMENTS AND CONTINGENCIES (Continued)

Capricor leases facilities from Cedars-Sinai Medical Center ("CSMC") pursuant to a lease (the "Facilities Lease") that was originally effective for a three-year period beginning June 1, 2014. Capricor has subsequently entered into several amendments extending the term of the lease and modifying its terms. From August 1, 2017 through March 1, 2019, total monthly rent was $19,756. Effective March 1, 2019, the square footage of the leased premises was reduced, resulting in a rent reduction of approximately $4,000 per month. In July 2019, Capricor exercised an option to extend the term of the Facilities Lease for an additional 12-month period through July 31, 2020 with a monthly lease payment of $15,805. In June 2020, the Company exercised its option to extend the term of the Facilities Lease for an additional 12-month period through July 31, 2021.

Included within the table below, future minimum rental payments to related parties totaled $205,465. A summary of future minimum rental payments required under operating leases as of June 30, 2020 is as follows:

Years ended	Operating Leases
2020 (6 months)	$ 192,204
2021	110,635

Expenses incurred under operating leases to unrelated parties for the three months ended June 30, 2020 and 2019 were $48,687 and $77,601, respectively, and $97,374 and $162,202 for the six months ended June 30, 2020 and 2019, respectively. Expenses incurred under operating leases to related parties for each of the three months ended June 30, 2020 and 2019 were $47,415 and $94,830 and $102,732 for the six months ended June 30, 2020 and 2019, respectively.

Legal Contingencies

The Company is not a party to any material legal proceedings at this time. From time to time, the Company may become involved in various legal proceedings that arise in the ordinary course of its business or otherwise.

Accounts Payable

Over the normal course of business, disputes with vendors may arise. If a vendor dispute payment is probable and able to be estimated, we will record an estimated liability.

Employee Severances

In the event of a termination, subject to certain conditions, the Board of Directors approved severance packages for specific full-time employees based on their length of service and position ranging up to six months of their base salaries. No liability has been recorded as of June 30, 2020.

8. 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 certain cardiac-derived cells with Università Degli Studi Di Roma La Sapienza (the "University of Rome"), The Johns Hopkins University ("JHU") and CSMC. In addition, Capricor has filed patent applications related to 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. Capricor has a right of first negotiation, for a certain period of time, to obtain a license to any new and separate patent applications owned by the University of Rome utilizing cardiac stem cells in cardiac care.

8. LICENSE AGREEMENTS (Continued)

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 may terminate the agreement upon the other party's material breach, provided that the breaching party will have up to 90 days to cure its material breach. Capricor may also terminate for any reason upon 90 days' written notice to the University of Rome.

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. Under the JHU License Agreement, Capricor is required to exercise commercially reasonable and diligent efforts to develop and commercialize licensed products covered by the licenses from JHU.

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. The next milestone is triggered upon successful completion of a full Phase II study for which a payment of $250,000 will be due. At this time, it is uncertain as to whether the $250,000 milestone payment will become due.

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.

8. LICENSE AGREEMENTS (Continued)

Cedars-Sinai Medical Center License Agreements

License Agreement for CDCs

On January 4, 2010, Capricor entered into an Exclusive License Agreement with CSMC (the "Original CSMC License Agreement") for certain intellectual property related to its CDC technology. In 2013, the Original 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") which amended, restated, and superseded the Original 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 for any future rights, Capricor will have a non-exclusive license to such future rights, subject to royalty obligations.

Pursuant to the Original 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 ranged 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) after 90 days' notice from CSMC 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. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights, and fails to cure that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. 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 (the "Second License Amendment"), pursuant to which the parties agreed to add certain patent applications to the schedule of patent rights set forth in the agreement. Under the Second License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes six additional patent applications; (ii) Capricor paid an upfront fee of $2,500; and (iii) Capricor reimbursed CSMC approximately $10,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent applications.

8. LICENSE AGREEMENTS (Continued)

On December 26, 2017, Capricor entered into a Third Amendment to the Amended CSMC License Agreement thereby amending the CDCs License (the "Third License Amendment"). Under the Third License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes seven additional patent applications; and (ii) Capricor is required to reimburse CSMC approximately $50,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent rights.

On June 20, 2018, Capricor and CSMC entered into a Fourth Amendment to the Amended CSMC License Agreement (the "Fourth License Amendment"). Under the Fourth License Amendment, the description of scheduled patent rights has been replaced by a revised schedule that includes two additional patent applications.

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 preparation and prosecution of certain patent applications. 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) after 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. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights, and fails to cure that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. 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 scheduled patent rights has been replaced by a revised schedule that includes four additional patent applications; (ii) Capricor was required to pay CSMC an upfront fee of $20,000; (iii) Capricor was 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.

8. LICENSE AGREEMENTS (Continued)

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 applications to the schedule of patent rights under the agreement. Under the Third Exosomes License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes three additional patent applications; (ii) Capricor paid CSMC an upfront fee of $2,500; and (iii) Capricor reimbursed CSMC approximately $16,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent applications.

On December 26, 2017, Capricor and CSMC entered into a Fourth Amendment to Exosomes License Agreement, thereby amending the Exosomes License (the "Fourth Exosomes License Amendment"). Under the Fourth Exosomes License Amendment, (i) the description of scheduled patent rights was replaced by a revised schedule that includes seven additional patent applications; (ii) Capricor is required to reimburse CSMC approximately $50,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent rights; and (iii) a schedule to the Exosomes License was modified to extend the milestone deadline for filing an IND for at least one product to December 31, 2018.

On June 20, 2018, Capricor and CSMC entered into a Fifth Amendment to the Exosomes License Agreement (the "Fifth License Amendment"). Under the Fifth License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes four additional patent applications; and (ii) Capricor is required to reimburse CSMC approximately $27,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent rights.

On September 25, 2018, Capricor and CSMC entered into a Sixth Amendment to the Exosomes License Agreement (the "Sixth License Amendment"). Under the Sixth License Amendment, the milestone deadline for filing an IND for at least one product was extended to December 31, 2019. If the Company did not file an IND by December 31, 2019, or negotiate an additional extension of the milestone deadline, CSMC had the option to convert the exclusive license to a non-exclusive license or to a co-exclusive license or terminate the license under Title 35, Section 203 of the United States Code. Prior to exercising such option, Capricor had the opportunity to cure the failure to file an IND for a period of 90 days after its receipt of written notice from CSMC of its intent to exercise its option. In the first quarter of 2020, Capricor received a notice from CSMC indicating that Capricor was in default of this milestone and further, that unless such default was cured by April 19, 2020, the Exosomes License Agreement would automatically terminate. On April 15, 2020, Capricor filed an IND with the FDA, satisfying its milestone requirement under the Exosomes License Agreement and has therefore cured such default.

Initiation of Sponsored Research Agreement

On April 1, 2020 we entered into a Sponsored Research Agreement ("SRA"), with Johns Hopkins University pursuant to which researchers in the lab of Dr. Stephen Gould will perform certain research activities in connection with our exosomes program. Pursuant to the SRA, we have agreed to fund the research activities and will have the right to negotiate for exclusive or non-exclusive rights to intellectual property that may result from such research activities.

9. RELATED PARTY TRANSACTIONS

Lease and Sub-Lease Agreement

As noted above, Capricor is a party to lease agreements with CSMC, which holds shares of capital stock of Capricor Therapeutics (see Note 7 – "Commitments and Contingencies"), and CSMC has served as an investigative site in Capricor's clinical trials. Additionally, Dr. Eduardo Marbán, who is a stockholder of Capricor Therapeutics and has participated from time to time as an observer at the Company's meetings of the Board of Directors, is the Director of the Cedars-Sinai Smidt Heart Institute, and co-founder of Capricor.

On April 1, 2013, Capricor entered into a sublease with Reprise Technologies, LLC, a limited liability company which is wholly owned by Dr. Frank 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 six months periods ended June 30, 2020 and 2019, Capricor recognized $15,000 in sublease income from the related party. Sublease income is recorded as a reduction to general and administrative expenses.

9. RELATED PARTY TRANSACTIONS (Continued)

Consulting Agreements

In 2013, Capricor entered into a Consulting Agreement with Dr. Frank Litvack, the Company's Executive Chairman and a member of its Board of Directors, whereby Capricor agreed to pay Dr. Litvack $10,000 per month for consulting services. The agreement is terminable upon 30 days' notice.

In July 2020, Capricor entered into an Advisory Services Agreement with Dr. Eduardo Marbán whereby he was granted an option to purchase 50,000 shares of the Company's common stock.

Payables to Related Party

At June 30, 2020 and December 31, 2019, the Company had accounts payable and accrued expenses to related parties totaling $16,440 and $22,315, respectively. CSMC accounts for $6,440 and $12,315 of the total accounts payable and accrued expenses to related parties as of June 30, 2020 and December 31, 2019, respectively. CSMC expenses relate to research and development costs, license and patent fees, and facilities rent. During the six months ended June 30, 2020 and 2019, the Company paid CSMC approximately $181,000 and $200,000, respectively, for such costs.

Related Party Clinical Trials

Capricor has agreed to provide CAP-1002 for investigational purposes in two clinical trials sponsored by CSMC. This product was developed as part of the Company's past research and development efforts. The first trial is known as "Regression of Fibrosis and Reversal of Diastolic Dysfunction in HFpEF Patients Treated with Allogeneic CDCs", or REGRESS. Dr. Eduardo Marbán is the named principal investigator under the study. In March 2020, we were informed that the REGRESS study was put on clinical hold by the FDA. The information we received suggested that the issue was related to inadequate patient monitoring at the study site to assess safety for certain patients who were experiencing adverse events after receiving an intracoronary infusion of CAP-1002. Inadequate patient monitoring and reporting was further discussed in additional correspondence from the FDA which we have subsequently received from the study sponsor. It remains uncertain as to when or if the FDA will release the clinical hold. The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells" or ALPHA. In both studies, Capricor will provide the necessary number of doses of cells and will receive a negotiated amount of monetary compensation which is estimated to be approximately $2.1 million over several years. For the six months ended June 30, 2020 and 2019, the Company recognized approximately $67,000 and $283,000, respectively, as revenue. As of June 30, 2020, and December 31, 2019, approximately $385 and $58,000, respectively, is outstanding and recorded in prepaid expenses and other current assets. As of June 30, 2020, there remains approximately $0.6 million to be received by the Company, subject to enrollment and certain conditions under the agreements. Due to the current COVID-19 pandemic, additional testing in the ALPHA trial has been delayed and as a result, purchases of additional doses of CAP-1002 have been delayed. Due to the clinical hold imposed on the REGRESS trial, purchases of additional doses of CAP-1002 have been suspended.

10. SUBSEQUENT EVENTS

None

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., our wholly-owned subsidiary.

Overview

Capricor Therapeutics, Inc. is a clinical-stage biotechnology company focused on the discovery, development and commercialization of innovative cell and exosome-based therapies for the treatment and prevention of diseases.

CAP-1002 - Duchenne Muscular Dystrophy Program

We have completed HOPE-2, a Phase II clinical trial in the United States with our product candidate, CAP-1002, a cardiac cell derived therapy which was used to treat patients with late-stage DMD. The 12-month final top-line data showed improvements in multiple measures of upper limb, cardiac and respiratory function. We recently discussed this program with the FDA in a Type B meeting focusing on the data, next steps and a pathway to approval of a Biologics Application License, or BLA for CAP-1002 in DMD. Consistent with our previous disclosures, the FDA has continued to encourage us to conduct a Phase III study, however at this time, we are still discussing the pathway forward for this program with the FDA.

CAP-1002 - COVID-19 Program

Additionally, under Expanded Access Emergency Use, seven patients hospitalized with severe COVID-19 symptoms, six of whom were ventilated, were treated with CAP-1002. Four of the seven patients were fully discharged and three died between one to two months post-treatment. Previously published data has shown that COVID-19 patients on ventilators experience high mortality rates. While we are unable to definitively ascertain whether CAP-1002 improved patient outcomes, by analyzing blood samples and other tests, it was determined that CAP-1002 demonstrated identifiable improvements in certain patients such as a decrease in white blood cell count, a decrease in IL-6, a decrease in C-reactive protein, and/or reduced reliance on supplemental oxygen. However, the efficacy of CAP-1002 in treating COVID-19 was not necessarily demonstrated due to the small sample size, the fact that seven patients were contemporaneously on other experimental medications, and no control group was established.

Additionally, we have been approved by the FDA to treat up to 20 patients under an Expanded Access IND protocol. However, we have shifted our focus to conducting a Phase II, randomized, placebo-controlled, double-blind study to further assess safety and efficacy of CAP-1002 in patients with severe or critical COVID-19. We are currently finalizing clinical operation activities to initiate this study. This next study is intended to treat up to 60 patients. We are working towards FDA approval to commence this larger study.

Exosomes Program

We have also begun work on developing our exosomes platform technology as a next-generation vaccine and therapeutic platform investigating a variety of disorders. We are currently engaged in the development of two vaccine candidates for the potential prevention of COVID-19. Pre-clinical studies have shown an antibody response using an mRNA vaccine approach. Concurrently, we are developing our clinical strategy to further evaluate these vaccine candidates.

In April 2020, we filed an IND with the FDA to investigate the use of CAP-2003 in patients with DMD. We are currently evaluating the next steps for this program and are planning to submit further information to FDA to support the potential approval of this IND.

Our executive offices are located at 8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211. Our telephone number is (310) 358-3200 and our Internet address is *www.capricor.com*.

Our Technologies

Cardiosphere-Derived Cells (CAP-1002)

Our core therapeutic technology is based on cardiosphere-derived cells, or CDCs, a cardiac-derived cell therapy that was first identified in the academic laboratory of Capricor's scientific founder, Dr. Eduardo Marbán. Since the initial publication in 2007, CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to approximately 200 human subjects across several clinical trials. CDCs have been shown to exert potent immunomodulatory activity and to alter the immune system's activity to encourage cellular regeneration. We have been developing allogeneic CDCs (CAP-1002) as a product candidate for the treatment of Duchenne muscular dystrophy, or DMD, and investigating their effects on skeletal and cardiac function. Pre-clinical and clinical data support the therapeutic concept of administering CDCs as a means to address conditions in which the heart or skeletal muscle has been damaged.

In a variety of preclinical experimental models of heart injury, CDCs have been shown to stimulate cell proliferation and blood vessel growth and to inhibit programmed cell death and scar formation. Published data by Cedars-Sinai Medical Center, or CSMC, which tested the effectiveness of CDCs in a mouse model of DMD, showed for the first time that the skeletal and cardiac improvements could be directly attributed to treatment with CDCs. The data also provide further evidence of the potential of CDCs to stimulate tissue repair and regeneration by first reducing inflammation, which then enables new healthy muscle to form, as was shown in the mouse model of DMD.

CDCs are derived from cardiospheres, or CSps, which are self-adherent multicellular clusters derived from the heart. CDCs are sufficiently small that, within acceptable dose limits, they can be infused into a coronary artery or into the peripheral vasculature. Capricor has performed clinical studies to establish the range of CDC dose levels that appear to be safe via intracoronary administration or peripheral venous access.

While CDCs originate from either a deceased human donor (allogeneic source) or from heart tissue taken directly from recipient patients themselves (autologous source), the methods for manufacturing CDCs from either source are similar.

Capricor's proprietary manufacturing methods are focused on producing therapeutic doses of CDCs to boost the regenerative capacity of the heart and skeletal muscles, with the goal of improving cardiac and skeletal muscle function. Capricor has exclusively licensed intellectual property covering CDCs and CSps from three academic institutions and is also pursuing its own intellectual property rights relating to CDCs as a product candidate.

Exosomes

Our preclinical data has shown that cardiosphere-derived cells mediate most of their therapeutic activities through the secretion of extracellular vesicles. Extracellular vesicles, including exosomes and microvesicles, are nano-scale, membrane-enclosed vesicles which are secreted by most cells and contain characteristic lipids, proteins and nucleic acids such as mRNA and microRNAs. They can signal through the binding and activation of membrane receptors or through the delivery of their cargo into the cytosol of target cells.

Exosomes act as messengers to regulate the functions of neighboring or distant cells and have been shown to regulate functions such as cell survival, proliferation, inflammation and tissue regeneration. Furthermore, pre-clinical research has shown that exogenously-administered exosomes can modify cellular activities, thereby supporting their therapeutic potential. Their size, low or null immunogenicity and ability to communicate in native cellular language potentially makes them an exciting new class of therapeutic agents with the potential to expand our ability to address complex biological responses. Because exosomes are a cell-free substance, they can be stored, handled, reconstituted and administered in similar fashion to common biopharmaceutical products such as antibodies.

CAP-1002 for the Treatment of Duchenne Muscular Dystrophy:

Based on our understanding of the mechanism of action of CAP-1002 which has been seen in pre-clinical models of DMD, we believe that CAP-1002 has the potential to decrease inflammation and muscle degeneration while exerting positive effects on muscle regeneration, all of which may translate into patients retaining muscle function for a longer period of time. Data supporting peripheral intravenous route of administration of CAP-1002 in the DMD setting has been provided by pre-clinical mouse studies where CDCs, the active ingredient in CAP-1002, have been shown to increase exercise capacity and diaphragmatic function.

We are currently developing CAP-1002 for the treatment of DMD. We completed the positive HOPE-Duchenne Phase I/II trial in 2017 and then subsequently began the HOPE-2 Phase II trial in 2018. We reported positive interim 6-month results from HOPE-2 in the third quarter of 2019 and we recently reported final top-line 12-month results. Our further plans with respect to the clinical development of CAP-1002 in DMD, including our decision to conduct a Phase III trial, will be based on the final guidance received from the FDA, our ability to secure funding necessary to conduct the trial should we decide to pursue that path and/or our ability to partner with another company to advance the development of CAP-1002 for DMD, as well as other factors, some of which are not known at this time.

Phase II HOPE-2 Clinical Trial

HOPE-2 is a randomized, double-blind, placebo-controlled clinical trial which was conducted at multiple sites located in the United States. We randomized 20 patients in our HOPE-2 clinical trial. Approximately 80% of the patients were non-ambulant and all patients were on a stable regimen of steroids. Demographic and baseline characteristics were similar between the two treatment groups. The clinical trial was designed to evaluate the safety and efficacy of repeat, intravenous, or IV, doses of CAP-1002, in boys and young men with evidence of skeletal muscle impairment regardless of ambulatory status and who are on a stable regimen of systemic glucocorticoids.

While there are many clinical initiatives in DMD, HOPE-2 is one of the very few to focus on non-ambulant patients. These boys and young men are looking to maintain what function they have in their arms and hands, and Capricor's previous study of a single intracoronary dose of CAP-1002 provided preliminary evidence of efficacy that CAP-1002 may be able to help DMD patients retain or slow the loss of upper limb function.

The primary efficacy endpoint of the HOPE-2 trial is the relative change in patients' abilities to perform manual tasks that relate to activities of daily living and are important to their quality of life. These abilities were measured through the Performance of the Upper Limb, or PUL, test. In the HOPE-2 study we have evaluated these through both the PUL 1.2 and 2.0 versions. Although the PUL 1.2 version for the mid-level was the primary endpoint established for the trial, we also conducted an analysis using the PUL 2.0 version as the FDA suggested the use of the updated PUL 2.0 version as the primary efficacy endpoint in support of a Biologics License Application, or BLA. HOPE-2 focused on the mid-level dimension of the PUL which assesses the ability to use muscles from the elbow to the hand, which are essential for operating wheelchairs and performing other daily functions. In HOPE-2, additional secondary and exploratory endpoints such as cardiac function, pulmonary function, quality of life and additional measures were included.

In July 2019, we reported interim top-line results from the HOPE-2 trial which showed that a pre-specified interim analysis performed on 6-month data showed meaningful results across several independent clinical measures.

In October 2019, we reported additional data from the interim analysis at the 24th Annual International Congress of the World Muscle Society. Data from a total of 20 patients was analyzed (12 placebo and 8 treated) at the 3- and 6-month time-point in the intent to treat (ITT) population. The late breaking podium presentation presented the top-line, 6-month results from the HOPE-2 clinical trial which showed meaningful results across several independent clinical measures.

In May 2020, we reported final top-line 12-month results. The data showed improvements in upper limb, cardiac and respiratory function with p-values of less than p=0.05 in multiple measures. The 12-month data showed statistically meaningful improvements in the PUL 2.0 in CAP-1002 treated patients (p=0.05) with a mean change of 2.4 points over placebo patients. We also came very close to significance with the PUL 1.2 mid-level with all the data (p=0.08) with a mean change of 2.8 points over placebo patients. With the exception of steroids, preservation of function in DMD is uncommon. The placebo patients declined consistent with natural history, but in the treated group, most patients were stable or improved throughout the one-year treatment period.

The data also showed global improvements in cardiac function as measured by ejection fraction (p=0.004) and indexed volumes (LVESV, p=0.01, LVEDV p=0.07). These are surrogate measures of cardiac function and are considered the "gold standard" in terms of relevance to long term outcomes. Additionally, there was also a reduction in the biomarker CK-MB, an enzyme that is only released when there is cardiac muscle cell damage. In normal human subjects, there is typically no CK-MB measurable in the blood. It is well accepted that continuous muscle cell damage in DMD leads to pathologically high enzyme levels associated with cardiac muscle cell loss. HOPE-2 demonstrated a reduction in CK-MB levels as compared to placebo (p=0.006). This is the first ever study in DMD that correlates cardiac functional stabilization with reduction of a biomarker of cell damage.

To assess pulmonary function, investigators measured several clinically relevant parameters. At 12 months, inspiratory flow reserve (absolute), a reflection of diaphragmatic strength, showed an improvement. Additionally, an improvement was observed at 12 months in peak expiratory flow (% predicted), another measure of diaphragmatic strength.

Study Results

12-month Top-Line Efficacy Data:

	12-month Time-point		
	CAP-1002 n=8	**Placebo n=12**	**p-value**
Upper Limb Function			
Mid-level PUL (version 1.2)	-2.1 (3.63)	-4.9 (2.57)	p=0.08
Shoulder + Mid + Distal PUL (version 1.2)	-2.3 (3.86)	-6.4 (3.84)	p=0.03
Shoulder + Mid + Distal PUL (version 2.0)	-1.3 (2.14)	-3.7 (1.50)	p=0.05
Cardiac			
LV Ejection Fraction %	-0.33 (2.01)	-1.89 (2.23)	p=0.004
LV End-Diastolic Volume, Indexed mL/m^2	-7.35 (6.10)	0.00 (7.34)	p=0.07
LV End-Systolic Volume, Indexed mL/m^2	-3.10 (1.68)	1.70 (5.02)	p=0.01
Creatine Kinase-MB (% of total CK)	-0.50 (0.55)	2.00 (1.00)	p=0.006

Mean Change from baseline to 12 months (standard deviation) shown.
ITT (intent to treat) population shown
P-values are nominal values unadjusted for multiple testing
Mixed model repeated measures analysis

Safety

CAP-1002 was generally safe and well tolerated throughout the study. With the exception of hypersensitivity reactions which were mitigated with a common pre-medication regimen, no safety signals were identified in the HOPE-2 trial.

Regulatory Developments

In June 2017, we had a meeting with the FDA to discuss potential clinical endpoints that could be used for registration strategies for CAP-1002 in the DMD indication. The minutes of the meeting indicated the FDA's willingness to accept Capricor's proposal to use the PUL test as the basis for the primary efficacy endpoint for clinical studies in support of a BLA. The PUL test is an outcome instrument that was specifically designed to assess upper limb function in ambulant and non-ambulant patients with DMD.

In December 2018, we met with the FDA as part of the expedited review afforded under the RMAT designation. The agency stated that the trial would need to provide evidence of clinically meaningful changes in the PUL, as well as other evidence supportive of CAP-1002 efficacy for patients with advanced Duchenne muscular dystrophy, in order to potentially serve as a registration trial.

In October 2019, we had a meeting with the FDA to discuss, among other things, the results of the 6-month interim analysis of the HOPE-2 trial and our path forward with our DMD program. During the meeting, we proposed the possibility of accelerated approval. The FDA was not supportive of an accelerated approval pathway at that time and noted that the HOPE-2 trial was designed as an exploratory trial and that the 6-month data from the HOPE-2 trial did not provide substantial evidence of effectiveness to support a future biologics license application, or BLA. The FDA did, however, indicate its support for conducting a Phase III trial of CAP-1002 for the treatment of DMD. In addition, the FDA reiterated that as part of our RMAT designation, they are willing to work with us to further the clinical development of the therapy.

In a follow-up to the October 2019 meeting, Capricor requested an additional meeting to clarify endpoints for future clinical trials. In a written response, FDA supported the use of the full PUL 2.0 from baseline to twelve months as a primary efficacy endpoint as long as clinical meaningfulness can be demonstrated. They suggested that a 1.0 point difference appears suitable to demonstrate product efficacy to support a BLA.

In a recent Type B meeting with the FDA, we focused on the 12-month results from the HOPE-2 trial and discussed next steps and a pathway to approval of a Biologics Application License, or BLA for CAP-1002 in DMD. Consistent with our previous disclosures, the FDA has continued to encourage us to conduct a Phase III study, however at this time, we are still discussing the pathway forward for this program with the FDA.

Additionally, we have initiated a technology transfer with a leading global CMO to prepare for commercial manufacturing of CAP-1002.

Additionally, we have initiated an open-label extension available to all patients who participated in the HOPE-2 study which includes those patients who received placebo.

Phase I/II HOPE-Duchenne Clinical Trial

We have completed the randomized, controlled, multi-center Phase I/II HOPE-Duchenne clinical trial which was designed to evaluate the safety and exploratory efficacy of CAP-1002 in patients with cardiomyopathy associated with Duchenne muscular dystrophy, or DMD. Twenty-five patients were randomized in a 1:1 ratio to receive either CAP-1002 on top of usual care or usual care only. In patients receiving CAP-1002, 25 million cells were infused into each of their three main coronary arteries for a total dose of 75 million cells. It was a one-time treatment, and the last patient was infused in September 2016. Patients were observed over the course of 12 months. Efficacy was evaluated according to several exploratory outcome measures. This study was funded in part through a grant award from the California Institute for Regenerative Medicine, or CIRM. In January 2019, this study was published in the online issue of *Neurology*, the medical journal of the American Academy of Neurology.

We reported our 12-month data from the HOPE-Duchenne trial at a Late-Breaking Science session of the American Heart Association Scientific Sessions 2017.As shoulder function had already been lost in most of the HOPE participants, investigators used the combined mid-distal PUL subscales to assess changes in skeletal muscle function and found significant improvement in those treated with CAP-1002 in a defined post-hoc analysis. Among the lower-functioning patients, defined as patients with a baseline mid-distal PUL score < 55 out of 58, investigators reported sustained or improved motor function at 12 months in 8 of 9 (89%) patients treated with CAP-1002 as compared to none (0%) of the usual care participants (p=0.007). Additionally, we reported significant improvements in systolic thickening of the left ventricular wall as well as reduction in scarring of the heart muscle among those treated with CAP-1002 decreased relative to the control group.

CAP-1002 was generally safe and well-tolerated in the HOPE-Duchenne trial. There was no significant difference in the incidence of treatment-emergent adverse events in either group. There were no early study discontinuations due to adverse events.

Regulatory Designations for CAP-1002 for the treatment of DMD

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 United States or a disease or condition that affects more than 200,000 people in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. 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 United States upon FDA approval.

In July 2017, the FDA granted Rare Pediatric Disease Designation to CAP-1002 for the treatment of DMD. The FDA defines a "rare pediatric disease" as a serious or life-threatening disease affecting individuals primarily aged from birth to 18 years and that affects fewer than 200,000 individuals in the United States. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, upon the approval of a qualifying New Drug Application, or NDA, or BLA for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for a Rare Pediatric Disease Priority Review Voucher that can be used to obtain priority review for a subsequent NDA or BLA. The Priority Review Voucher may be sold or transferred an unlimited number of times.

In February 2018, we were notified by the FDA Office of Tissues and Advanced Therapies, that we were granted the Regenerative Medicine Advanced Therapy, or RMAT, designation for CAP-1002 for the treatment of DMD. The FDA grants the RMAT designation to regenerative medicine therapies intended to treat a serious condition and for which preliminary clinical evidence indicates a potential to address unmet medical needs for that condition. The RMAT designation makes therapies eligible for the same actions to expedite the development and review of a marketing application that are available to drugs that receive breakthrough therapy designation – including increased meeting opportunities, early interactions to discuss any potential surrogate or intermediate endpoints and the potential to support accelerated approval. CAP-1002 is one of the few therapies currently in development to help non-ambulant patients with DMD. To receive the RMAT designation, we submitted data from the HOPE-Duchenne Trial.

CAP-1002 for the Treatment of Cardiac Conditions:

In previous years, we completed several trials investigating the use of CAP-1002 for the treatment of various cardiac conditions, including heart failure (the DYNAMIC Trial) and post myocardial infarction (MI) with cardiac dysfunction (ALLSTAR). Because of our decision to focus our efforts on DMD, we have decided not to pursue those indications at this time, nor do we have any plans to continue with the development of these programs although we are continuing to evaluate certain cardiac measures in our HOPE-2 trial. We expect no further material expenses in connection with these programs.

CAP-1002 - Investigator Sponsored Clinical Trials:

Capricor has agreed to provide cells for investigational purposes in two clinical trials sponsored by CSMC. These cells were developed as part of the Company's past research and development efforts. The first trial is known as "Regression of Fibrosis and Reversal of Diastolic Dysfunction in HFpEF Patients Treated with Allogeneic CDCs." Dr. Eduardo Marbán is the named principal investigator under the study. In March 2020, we were informed that the REGRESS study was put on clinical hold by the FDA. The information we received suggested that the issue was related to inadequate patient monitoring at the study site to assess safety for certain patients who were experiencing adverse events after receiving an intracoronary infusion of CAP-1002. Inadequate patient monitoring and reporting was further discussed in additional correspondence from the FDA which we have subsequently received from the study sponsor. It remains uncertain as to when or if the FDA will release the clinical hold. It is worth noting that Capricor did not use intracoronary infusions in its HOPE-2 trial. The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells." In this trial, the investigational product is infused into the venous system via catheter into the right atrium. This trial is currently ongoing. In both studies, Capricor is providing the necessary number of doses of cells and will receive a negotiated amount of monetary compensation which was estimated to be approximately $2.1 million over several years. Due to the current COVID-19 pandemic, additional testing in the ALPHA has been delayed and as a result, purchases of additional doses of CAP-1002 have been delayed. Due to the clinical hold imposed on the REGRESS trial, purchases of additional doses of CAP-1002 have been suspended.

Exosomes Program

Our exosomes program consists of exosomes derived from CDCs (CAP-2003) and engineered exosomes, both of which are in various stages of preclinical development. We have explored the use of our CDC-exosomes in pre-clinical studies of inflammation and intense immune activation such as DMD, sepsis, Graft versus-host disease (GVHD) and trauma. While CDC-exosomes are the initial technology we have used in preclinical development, we have expanded Capricor's pipeline to include additional exosome technologies. We are now focused on developing a precision-engineered exosome platform technology that can carry defined sets of effector molecules which exert their effects through defined mechanisms of action. We have begun work on our planned expansion of our exosome platform technology that potentially may be used for vaccine development, vesicle mediated protein therapies and treatment of inherited diseases.

Engineered Exosomes Vaccine Platform for COVID-19

To build upon the natural ability of exosomes for intercellular communication, we have initiated a program to engineer exosomes and load them with different macromolecules. We are now working on developing exosome-based vaccines for COVID-19. The exosome-based vaccine platform technology will aim to combine the improved protection that comes from immunizing individuals with multiple antigens in a manner that mimics the advantages of conventional virus vaccines, with the superior safety profile of virus-free vaccines. We are currently designing exosome-based vaccines to elicit strong humoral and cellular immune responses due to the simultaneous expression of antigens. We are developing two exosome vaccine candidates. The first vaccine candidate is a tripartite exosome/mRNA vaccine which is designed to elicit a protective, long-lasting immune response to SARS-CoV-2 by targeting all 4 structural proteins of the virus. The second candidate is an exosomal antigen vaccine which is a vesicle-based, nucleic acid-free formulation carrying all structural proteins of SARS-CoV-2. These efforts are now well underway in animal studies and the mRNA vaccine has shown to be capable of generating an antibody response to multiple antigens expressed by COVID-19. Concurrently, we are developing our clinical strategy to further evaluate these vaccine candidates.

In conjunction with these efforts, we have entered into a Sponsored Research Agreement with Johns Hopkins University pursuant to which researchers in the lab of Dr. Stephen Gould will perform certain research activities in connection with our exosomes program.

Other Indications for our Exosomes Technologies

We have promising pre-clinical data in several indications from studies done in our labs as well as in collaboration with other companies and academic institutions. Additionally, in July 2018, we entered into a Cooperative Research and Development Agreement with the U.S. Army Institute of Surgical Research (USAISR) pursuant to which we agreed to cooperate in research and development on the evaluation of our CDC-Exosomes for the treatment of trauma related injuries and conditions which are now the third leading cause of death in the U.S.

In April 2020, we filed an IND with the FDA to investigate the use of CAP-2003 in patients with DMD. We are currently evaluating the next steps for this program and are planning to submit further information to FDA to support the potential approval of this IND.

These programs represent our core technology and products.

Financial Operations Overview

We have no commercial product sales to date and will not have the ability to generate any commercial 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, consisting of CAP-1002 and exosomes. As we proceed with the clinical development of CAP-1002, and as we further develop exosomes, our expenses will further increase. 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 our products and our clinical programs. Our major sources of working capital to date have been proceeds from private and public equity sales of securities, grants received from the NIH and the Department of Defense, or DoD, a payment from Janssen under our now terminated Collaboration Agreement, and a loan and grant award from CIRM. While we pursue our pre-clinical and clinical programs, we continue to explore financing and other strategic alternatives with respect to the Company as well as one or more of our product candidates.

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs, supplies, clinical trial costs, patient treatment costs, rent for laboratories and manufacturing facilities, 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

Revenue

Grant Income. Grant income for the three months ended June 30, 2020 and 2019 was approximately $50,000 and $144,000, respectively. Grant income related to the DoD Grant Award. The decrease relates to the timing of the award as the DoD Grant Award is expected to be ending in September 2020.

Grant income for the six months ended June 30, 2020 and 2019 was approximately $0.2 million and $0.3 million, respectively.

Miscellaneous Income. Miscellaneous income for the three months ended June 30, 2020 and 2019 was zero and approximately $0.3 million, respectively. The miscellaneous income was related to providing cells for investigational purposes for clinical trials sponsored by CSMC. The decrease in miscellaneous income is due the current COVID-19 pandemic as the clinical trials sponsored by CSMC have been delayed or put on hold.

Miscellaneous income for the six months ended June 30, 2020 and 2019 was approximately $0.1 million and $0.4 million, respectively.

Operating Expenses

General and Administrative Expenses. G&A expenses for the three months ended June 30, 2020 and 2019 were approximately $1.6 million and $0.8 million, respectively. The increase of approximately $0.8 million in G&A expenses in the second quarter of 2020 compared to the same period of 2019 is primarily attributable to an increase of approximately $0.5 million in stock-based compensation expense. Furthermore, there was an increase of approximately $0.3 million attributable to an increase in salaries and other general expenses including investor relations and legal expenses.

G&A expenses for the six months ended June 30, 2020 and 2019 were approximately $2.7 million and $1.8 million, respectively. The increase of approximately $0.9 million in G&A expenses in the first half of 2020 compared to the same period of 2019 is primarily attributable to an increase of approximately $0.6 million in stock-based compensation expense. Additionally, there was an increase of approximately $0.4 million attributable to an increase in salaries and other general expenses including investor relations and legal expenses.

Research and Development Expenses. R&D expenses for the three months ended June 30, 2020 and 2019 were approximately $1.9 million and $1.6 million, respectively. The increase of approximately $0.3 million in R&D expenses in the second quarter of 2020 compared to the same period of 2019 is primarily due to the increase in research and development expenses related to our COVID-19 exosome vaccine program and manufacturing of CAP-1002 for our clinical programs. These activities resulted in an increase in expenses of approximately $0.8 million. Furthermore, there was an increase of approximately $0.2 million due to headcount/salaries and regulatory and a decrease of approximately $0.8 million associated with clinical development costs for CAP-1002 (HOPE-Duchenne, HOPE-2 and HOPE-OLE clinical trials).

R&D expenses for the six months ended June 30, 2020 and 2019 were approximately $3.1 million and $3.5 million, respectively. The decrease of approximately $0.4 million in R&D expenses in the first half of 2020 compared to the same period of 2019 is primarily due to the timing of clinical development activities of CAP-1002 (HOPE-Duchenne, HOPE-2 and HOPE-OLE clinical trials). These activities resulted in a decrease of approximately $1.2 million. Furthermore, there was an increase of approximately $0.6 million in research and development expenses related to our COVID-19 exosome vaccine program and manufacturing of CAP-1002 for the six months ended June 30, 2020 as compared to the same period in 2019. Additionally, there was an increase of $0.3 million in salaries/headcount and regulatory expenses in the first half of 2020 as compared to the same period of 2019.

Products Under Active Development

CAP-1002 – CAP-1002 is in its developmental stages. We expect to spend approximately $4.0 million to $6.0 million during 2020 on the further development of CAP-1002 for DMD and COVID-19, which expenses are primarily related to additional clinical, regulatory and manufacturing-related expenses. These figures are largely dependent on the next steps in our DMD and COVID-19 program, the regulatory status of our programs with the FDA, and our ability to secure a partner for the potential future further clinical development of CAP-1002 for DMD, if necessary and various other factors.

Exosome Technologies – We expect to spend approximately $3.0 million to $6.0 million during 2020 on pre-clinical and other research expenses related to our exosomes program. Capricor is currently engaged in pre-clinical testing of exosomes as a potential vaccine for COVID-19. Additionally, we have entered into a Sponsored Research Agreement with Johns Hopkins University for further research related to our exosomes technologies. Further, on April 15, 2020 we filed an IND with the FDA to investigate CAP-2003 in patients with DMD.

Our expenditures on current and future clinical development programs, particularly our CAP-1002 and exosomes programs, cannot be predicted with any significant degree of certainty as they are dependent on the results of our current trials and our ability to secure additional funding and a strategic partner. Further, 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.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of June 30, 2020 and December 31, 2019 and our net increase in cash, cash equivalents and restricted cash for the six months ended June 30, 2020 and 2019, 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, 2020**	**December 31, 2019**
Cash, cash equivalents and marketable securities	$ 36,253	$ 9,885
Working capital	$ 34,635	$ 9,647
Stockholders' equity	$ 31,654	$ 6,839

	Six months ended June 30,	
Cash flow data	**2020**	**2019**
Cash provided by (used in):		
Operating activities	$ (3,235)	$ (3,385)
Investing activities	5,879	2,985
Financing activities	29,709	1,979
Net increase in cash, cash equivalents, and restricted cash	$ 32,353	$ 1,579

Our total cash, cash equivalents and marketable securities as of June 30, 2020 was approximately $36.3 million compared to approximately $9.9 million as of December 31, 2019. The increase in cash, cash equivalents and marketable securities from December 31, 2019 as compared to June 30, 2020 is primarily due to net financing activities of approximately $29.7 million and a net loss of approximately $5.6 million for the six months ended June 30, 2020. As of June 30, 2020, we had approximately $5.5 million in total liabilities and approximately $34.6 million in net working capital.

Cash used in operating activities was approximately $3.2 million and $3.4 million for the six months ended June 30, 2020 and 2019, respectively. The difference of approximately $0.2 million in cash used in operating activities is due to an increase of approximately $1.0 million in net loss for the six months ended June 30, 2020 as compared to the same period in 2019. Furthermore, there was an increase of approximately $0.6 million in accounts payable and accrued liabilities and an increase of approximately $0.6 million in stock-based compensation for the six months ended June 30, 2020 as compared to the same period in 2019. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, including if 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 losses, which will generate negative net cash flows from operating activities.

We had cash flow provided by investing activities of approximately $5.9 million and $3.0 million for the six months ended June 30, 2020 and 2019, respectively. The increase in cash provided by investing activities for the six months ended June 30, 2020 as compared to the same period of 2019 is primarily due to the net effect from purchases, sales, and maturities of marketable securities.

We had cash flow provided by financing activities of approximately $29.7 million and $2.0 million for the six months ended June 30, 2020 and 2019, respectively. The increase in cash provided by financing activities for the six months ended June 30, 2020 is primarily due to the approximate $29.4 million in net proceeds received from the May 2020 ATM Program and exercise of common warrants.

From inception through June 30, 2020, we financed our operations primarily through private and public sales of our equity securities, NIH and DoD grants, a payment from Janssen, a CIRM loan and a CIRM grant award. As we have not generated any revenue from the commercial 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 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, government grants, 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, complete our clinical trials or if such funds become 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 and success 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, and the progress of efforts with parties with whom we may enter into commercial manufacturing agreements;
- our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;
- additional costs associated with maintaining licenses and insurance;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

As a result of the spread of the COVID-19 coronavirus, uncertainties have arisen that could potentially impact enrollment of clinical trials, deliverables related to contract performance, payments from trial sponsors, workforce stability, supply chain disruptions or delays, timing of grant disbursements as well as other potential business operations. While the disruption is currently expected to be temporary, there is considerable uncertainty around its expected duration. In addition to potential impact on grant disbursements, there may be risks to the Company's ability to obtain financing from other sources, due to the impact of the coronavirus. There could be other financial impacts on our business of the coronavirus, the specifics of which are unknown at this time.

Financing Activities by the Company

May 2020 ATM Program. On May 4, 2020, the Company initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $40.0 million, or the May 2020 ATM Program, with the common stock to be distributed at the market prices prevailing at the time of sale. The May 2020 ATM Program was established under a Common Stock Sales Agreement, or the July 2019 Sales Agreement, with H.C. Wainwright & Co. LLC, or Wainwright, under which we may, from time to time, issue and sell shares of our common stock through Wainwright as sales agent. The July 2019 Sales Agreement provides that Wainwright will be entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold. All shares issued pursuant to the July 2019 ATM Program were issued pursuant to our shelf registration statement on Form S-3 (File No. 333-227955), which was initially filed with the SEC on October 24, 2018, amended on July 17, 2019 and declared effective by the SEC on July 18, 2019. Since May 4, 2020 and through the date of this filing, the Company has sold an aggregate of 3,059,959 shares of common stock under the May 2020 ATM Program at an average price of approximately $6.59 per share for gross proceeds of approximately $20.2 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of Wainwright and legal fees in the aggregate amount of approximately $0.7 million.

March 2020 Warrant Inducement. On March 25, 2020, the Company entered into a letter agreement, or the Exercise Agreement, with a holder of December 2019 Common Warrants (as defined below), or the Exercising Holder. Pursuant to the Exercise Agreement, in connection with the exercise by the Exercising Holder of the remaining 4,000,000 December 2019 Common Warrants held by the Exercising Holder which had not been previously exercised, the Company agreed to issue 4,000,000 additional warrants, or the New Warrants, to purchase Common Stock. The December 2019 Common Warrants had a per share exercise price of $1.10, and pursuant to the Exercise Agreement, the Exercising Holder agreed to pay $1.225 per share to cover both the exercise price of the December 2019 Common Warrants and a $0.125 per share purchase price for the New Warrants. The New Warrants have an exercise price of $1.27 per share.

The New Warrants and the shares of Common Stock issuable upon the exercise of the New Warrants have not been registered under the Securities Act of 1933, as amended, or the Securities Act, and were offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act or Rule 506(b) promulgated thereunder. The New Warrants are exercisable immediately upon issuance, and have a term of exercise of 5 1/2 years.

The Company received aggregate gross proceeds of approximately $4.9 million from the exercise of the December 2019 Common Warrants by the Exercising Holder. These gross proceeds were reduced by fees due and payable to the placement agent for the transactions pursuant to the Exercise Agreement and New Warrants in the amount of $343,000, and further reduced by reimbursements to the placement agent for legal fees and other expenses. In addition, certain employees of the placement agent received new warrant, or the March 2020 Placement Agent Warrants, for shares of Common Stock equal to 5.0% of the New Warrants issued, or 200,000 shares. These March 2020 Placement Agent Warrants are exercisable immediately and have a term of exercise of 5 years. The holders of each of the New Warrants and of the March 2020 Placement Agent Warrants have the option to make a cashless exercise of such warrant if no resale registration statement covering the shares of the Company's Common Stock underlying such warrant is effective after six months. On May 7, 2020, the Company filed a resale registration statement on Form S-3 for the shares underlying the New Warrants and March 2020 Placement Agent Warrants, and that resale registration statement was declared effective by the SEC on May 19, 2020.

December 2019 Public Offering. In December 2019, the Company completed a public offering (the December Offering), pursuant to which the Company issued (i) 531,173 shares of its common stock, (ii) warrants, or the December 2019 Common Warrants, to purchase up to 4,139,477 shares of common stock, and (iii) pre-funded warrants to purchase up to 3,608,304 shares of common stock, at a combined purchase price of $1.226 per share and associated common warrant and $1.225 per pre-funded warrant and associated common warrant for an aggregate purchase price of approximately $5.1 million. The Company issued (a) to each purchaser of shares in the December Offering a common warrant to purchase a number of shares of common stock equal to the number of shares purchased by such purchaser in the December Offering, and (b) to each purchaser of pre-funded warrants in the December Offering a common warrant to purchase a number of shares of common stock equal to the number of pre-funded warrant shares underlying the pre-funded warrants purchased by such purchaser in the December Offering. All shares and warrants issued pursuant to the December Offering, other than the Placement Agent Warrants, were issued pursuant to our registration statement on Form S-1 (File No. 333-235358), which was initially filed with the Securities and Exchange Commission, or the SEC, on December 5, 2019, amended on December 13, 2019 and declared effective by the SEC on December 17, 2019. Fees paid in conjunction with the deal, which included placement agent commissions, management fees, legal costs, and other offering expenses, amount to approximately $0.7 million in the aggregate and were recorded as a reduction to additional paid-in capital, resulting in net proceeds of approximately $4.4 million. Since December 19, 2019 and through the date of this filing, all 3,608,304 pre-funded warrants and 78,304 common warrants have been exercised.

August 2019 ATM Program. On August 29, 2019, the Company initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $1.95 million, or the August 2019 ATM Program, with the common stock to be distributed at the market prices prevailing at the time of sale. The August 2019 ATM Program was established under the July 2019 Sales Agreement, which provides that Wainwright is entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold. All shares issued pursuant to the August 2019 ATM Program have been and will be issued pursuant to our shelf registration statement on Form S-3 (File No. 333-227955), which was initially filed with the SEC, on October 24, 2018, amended on July 17, 2019 and declared effective by the SEC on July 18, 2019. Since August 29, 2019 and through the date of filing, the Company has sold an aggregate of 360,316 shares of common stock under the August 2019 ATM Program at an average price of approximately $3.07 per share for gross proceeds of approximately $1.1 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of the placement agent and legal fees in the aggregate amount of approximately $0.1 million. As of May 4, 2020, the August 2019 ATM Program has expired and been replaced with the May 2020 ATM Program.

July 2019 ATM Program. On July 22, 2019, the Company initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $1.8 million, or the July 2019 ATM Program, with the common stock to be distributed at the market prices prevailing at the time of sale. The July 2019 ATM Program was established under the July 2019 Sales Agreement, which provides that Wainwright will be entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold. All shares issued pursuant to the July 2019 ATM Program were issued pursuant to our shelf registration statement on Form S-3 (File No. 333-227955), which was initially filed with the SEC on October 24, 2018, amended on July 17, 2019 and declared effective by the SEC on July 18, 2019. As of the expiration of the July 2019 ATM Program, the Company sold an aggregate of 418,450 shares of common stock under the July 2019 ATM Program at an average price of approximately $4.30 per share for gross proceeds of approximately $1.8 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of the placement agent and legal fees in the aggregate amount of approximately $0.1 million.

Financing Activities by Capricor, Inc.

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 were tied to the achievement of specified operational milestones. In addition, the terms of the CIRM Award included a co-funding requirement pursuant to which Capricor was required to spend approximately $2.3 million of its own capital to fund the CIRM funded research project. 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, California Code of Regulations (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 the 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 at any time after the award period end date (but no later than the ten-year anniversary of the date of the award), Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and development of the program 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 Capricor elects to convert the grant into a loan, the term of the loan could be up to five years from the date of execution of the applicable loan agreement; provided that the maturity date of the loan will not surpass the ten-year anniversary of the grant date of the CIRM Award. Beginning on the date of the loan, the loan shall bear interest on the unpaid principal balance, plus the interest that has accrued prior to the election point according to the terms set forth in CIRM's Loan Policy, or the 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 convert the CIRM Award into a loan, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements. Capricor has not yet made its decision as to whether it will elect to convert the CIRM Award into a loan. If we elect to do so, Capricor would be required to repay some or all of the amounts awarded by CIRM, therefore the Company accounts for this award as a liability rather than income.

As of June 30, 2020, Capricor's liability balance for the CIRM Award was approximately $3.4 million. In June 2019, Capricor completed all milestones associated with the CIRM Award and expended all funds received. In the third quarter of 2019, Capricor completed all final close-out documentation associated with this award.

U.S. Department of Defense Grant Award

In September 2016, Capricor was approved for a grant award from the DoD in the amount of approximately $2.4 million to be used toward developing a scalable, commercially-ready process to manufacture CAP-2003. Under the terms of the award, disbursements will be made to Capricor over a period of approximately three years, subject to annual and quarterly reporting requirements. The Company was granted a no-cost extension until September 29, 2020 to be able to continue to utilize these funds. As of June 30, 2020, approximately $2.3 million has been incurred under the terms of the award.

Contractual Obligations and Commitments

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

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, 2020.

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.

Leases

Effective January 1, 2019, the Company adopted ASC 842, using the optional transition method utilizing the effective date as its date of initial application, for which prior periods are presented in accordance with the previous guidance in ASC 840.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than 12 months are recognized on the balance sheet as right of use assets and short-term and long-term lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. The Company monitors its plans to renew its leases no less than on a quarterly basis. In addition, the Company's lease agreements generally do not contain any residual value guarantees or restrictive covenants.

Operating lease liabilities and their corresponding right of use assets are recorded based on the present value of future lease payments over the expected remaining lease term at lease commencement. Lease cost for operating leases is recognized on a straight-line basis over the lease term as an operating expense. Certain adjustments to the right of use asset may be required for items such as lease prepayments or incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rate.

In accordance with ASC 842, components of a lease should be bifurcated between lease components and non-lease components. The fixed and in-substance fixed contract consideration identified must then be allocated based on the respective relative fair values to the lease components and non-lease components. However, ASC 842 provides a practical expedient that allows an accounting policy election to not separate lease and non-lease components by class of underlying asset. In using this expedient, the lease component and non-lease components are accounted for together as a single component. For real estate leases, the Company has elected to account for the lease and non-lease components together for existing classes of underlying assets and allocates the contract consideration to the lease component only. This practical expedient is not elected for manufacturing facilities and equipment embedded in product supply arrangements.

Revenue Recognition

For contracts completed as of December 31, 2017, revenue was recognized in accordance with ASC 605 and other standards which have been superseded for subsequent fiscal years. The Company applied ASU 606 using the modified retrospective approach for all contracts in process as of January 1, 2018.

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. Grant income is due upon submission of reimbursement request. The transaction price varies for grant income based on the expenses incurred under the awards.

Miscellaneous Income

Revenue is recognized in connection with the delivery of doses which were developed as part of our past R&D efforts. Income is recorded when the Company has satisfied the obligations as identified in the contracts with the customer. Miscellaneous income is due upon billing. Miscellaneous income is based on contracts with fixed transaction prices.

CIRM Grant Award

Capricor accounts for the disbursements under its CIRM Award as long-term liabilities. Capricor recognizes the CIRM grant disbursements as a liability 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 convert the CIRM Award into 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.

Research and Development Expenses and Accruals

R&D expenses consist primarily of salaries and related personnel costs, supplies, clinical trial costs, patient treatment costs, rent for laboratories and manufacturing facilities, 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 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan (which superseded the 2006 Stock Option Plan), (iii) the 2012 Non-Employee Director Stock Option Plan, and (iv) the 2020 Equity Incentive Plan (the "2020 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, and the risk-free interest rate. We account for forfeitures upon occurrence.

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. The fair value of stock options is determined using the Black-Scholes option-pricing model. Historically, the Company periodically re-measured the fair value for non-qualified option grants recording an expense over the applicable vesting periods. However, in the third quarter of 2018, the Company early adopted ASU 2018-07. The Company calculates the fair value for non-qualified options as of the date of grant and expenses over the applicable vesting 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 and Comprehensive Income (Loss). We expect to record additional non-cash compensation expense in the future, which may be significant.

Restricted Cash

Prior to March 31, 2019, restricted cash represented funds received under the CIRM Award. Restricted cash funds were allocated to the research costs as incurred. Generally, a reduction of restricted cash occurs when the Company deems certain costs are attributable to the respective award. The Company fully utilized the CIRM Award in June 2019.

In April 2019, the Company entered into a letter of credit as a security deposit for its lease agreement for corporate office space.The Company delivered to the landlord a letter of credit in the amount of $232,803 to cover payments of rent for the remainder of the 2019 lease term, which was subsequently cancelled and the funds were returned to Capricor. As such, no restricted cash is recorded as of June 30, 2020.

Clinical Trial Expense

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. Our clinical trial accrual process is designed to account for expenses resulting from our obligations under contracts with vendors, consultants, and CROs and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by matching the appropriate expenses with the period in which services are provided and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models that take into account discussion with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on the facts and circumstances known to us at that time. Our clinical trial accrual and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period.

Recently Issued or Newly Adopted Accounting Pronouncements

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808):* clarifying the interaction between Topic 808 and Topic 606. The amendments in the update clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account; adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 when an entity is assessing whether the collaborative arrangement or a party of the arrangement is within the scope of Topic 606; requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The amendments for this update are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company adopted ASU 2018-18 and all subsequent updates related to this topic in the first quarter of 2020. The adoption of this update did not have a material impact on the Company's financial statements.

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 consolidated financial statement presentation or disclosures.

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, 2020, the fair value of our cash and cash equivalents was approximately $36.3 million. Additionally, as of June 30, 2020, Capricor's portfolio was classified as cash and cash equivalents, which consisted primarily of money market funds and bank money market, which included short term U.S. treasuries, bank savings and checking accounts.

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 U.S. 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, 2020 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 involved in any material pending legal proceedings and are not aware of any material threatened legal proceedings against us.

Item 1A. Risk Factors.

Part 1, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on March 27, 2020, describes important risk factors that could cause our business, financial condition, results of operations and prospects to differ significantly from those suggested by forward-looking statements made in this Quarterly Report on Form 10-Q or otherwise presented by us from time to time. Except as set forth below, there have been no material changes in our risk factors from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on March 27, 2020.

Risks Related to Clinical and Commercialization Activities

The clinical data we intend to generate for the COVID-19 indication may not be sufficient for regulatory approval, which could adversely affect our stock price.

While our announcement on April 29, 2020 of the treatment of patients with severe COVID-19 symptoms with CAP-1002 has caused significant investor attention resulting in a material increase in the market price of our Common Stock, we will need to successfully conduct at least one randomized, placebo-controlled clinical trial in order to further study and ultimately seek to commercialize CAP-1002 for this indication. We have submitted a new IND to conduct a randomized, double-blind, placebo-controlled Phase II trial to treat up to 60 patients in critical or severe condition with COVID-19, subject to approval by the FDA. Our stock price may suffer if this use for CAP-1002 is not successful in this or other future clinical trials.

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.

2.1	Agreement and Plan of Merger, dated as of August 15, 2007, by and among SMI Products, Inc., Nile Merger Sub, 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 SEC 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 SEC 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 SEC 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 SEC 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 SEC on November 26, 2013).
3.3	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 SEC on June 4, 2019).
3.4	Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 9, 2007).
10.1	Capricor Therapeutics, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-8, filed with the SEC on June 17, 2020).
10.2	Form of Stock Option Agreement for Capricor Therapeutics, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 4.10 to the Company's Registration Statement on Form S-8, filed with the SEC on June 17, 2020).
31.1	Certification of Principal Executive Officer.*
31.2	Certification of Principal Financial Officer.*
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certification of Principal Financial Officer 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, 2020 formatted in eXtensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of June 30, 2020 and December 31, 2019, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.*

* Filed herewith.

SIGNATURES

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

CAPRICOR THERAPEUTICS, INC.

Date: August 10, 2020

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

Date: August 10, 2020

By: /s/ Anthony J. Bergmann
Anthony J. Bergmann
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Linda Marbán, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Capricor Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2020

/s/ Linda Marbán, Ph.D.
Name: Linda Marbán, Ph.D.
Title: Chief Executive Officer and Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Anthony J. Bergmann, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Capricor Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2020

/s/ Anthony J. Bergmann
Name: Anthony J. Bergmann
Title: Chief Financial Officer and Principal Financial Officer

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Linda Marbán, Ph.D., the Principal Executive Officer of Capricor Therapeutics, Inc. (the "**Company**"), hereby certifies, to her knowledge, that:

(1) the Quarterly Report on Form 10-Q of the Company for the period ended June 30, 2020 (the "**Report**") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the Report.

Date: August 10, 2020

/s/ Linda Marbán, Ph.D.
Name: Linda Marbán, Ph.D.
Title: Chief Executive Officer and Principal Executive Officer

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Anthony J. Bergmann, the Principal Financial Officer of Capricor Therapeutics, Inc. (the "**Company**"), hereby certifies, to his knowledge, that:

(1) the Quarterly Report on Form 10-Q of the Company for the period ended June 30, 2020 (the "**Report**") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the Report.

Date: August 10, 2020

/s/ Anthony J. Bergmann
Name: Anthony J. Bergmann
Title: Chief Financial Officer and Principal Financial Officer