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 March 31, 2021**

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 May 13, 2021, there were 22,877,930 shares of the registrant's common stock, par value $0.001 per share, issued and outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "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 and vaccine candidates, including when we expect to undertake, initiate and complete clinical trials of our drug and vaccine 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 and vaccine 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;
- 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 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;
- 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

	March 31, 2021 (Unaudited)	December 31, 2020
CURRENT ASSETS		
Cash and cash equivalents	$ 41,879,554	$ 32,665,874
Prepaid expenses and other current assets	736,358	1,011,209
TOTAL CURRENT ASSETS	42,615,912	33,677,083
PROPERTY AND EQUIPMENT, net	838,705	850,847
OTHER ASSETS		
Intangible assets, net of accumulated amortization of $258,599 and $257,517, respectively	1,083	2,165
Other assets	88,701	88,701
TOTAL ASSETS	$ 43,544,401	$ 34,618,796
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 3,469,197	$ 2,724,593
Note payable, current	282,691	246,689
TOTAL CURRENT LIABILITIES	3,751,888	2,971,282
LONG-TERM LIABILITIES		
Note payable, net of current	35,469	71,471
CIRM liability	3,376,259	3,376,259
TOTAL LONG-TERM LIABILITIES	3,411,728	3,447,730
TOTAL LIABILITIES	7,163,616	6,419,012
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, 22,797,930 and 20,577,123 shares issued and outstanding, respectively	22,798	20,577
Additional paid-in capital	129,547,669	116,216,966
Accumulated other comprehensive income (loss)	—	—
Accumulated deficit	(93,189,682)	(88,037,759)
TOTAL STOCKHOLDERS' EQUITY	36,380,785	28,199,784
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 43,544,401	$ 34,618,796

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three months ended March 31,	
	2021	**2020**
REVENUE		
Revenue	$ 40,816	$ 185,693
TOTAL REVENUE	40,816	185,693
OPERATING EXPENSES		
Research and development	3,296,322	1,155,156
General and administrative	1,905,582	1,138,045
TOTAL OPERATING EXPENSES	5,201,904	2,293,201
LOSS FROM OPERATIONS	(5,161,088)	(2,107,508)
OTHER INCOME (EXPENSE)		
Investment income	9,165	22,690
TOTAL OTHER INCOME (EXPENSE)	9,165	22,690
NET LOSS	(5,151,923)	(2,084,818)
OTHER COMPREHENSIVE INCOME (LOSS)		
Net unrealized gain on marketable securities	—	757
COMPREHENSIVE LOSS	$ (5,151,923)	$ (2,084,061)
Net loss per share, basic and diluted	$ (0.23)	$ (0.30)
Weighted average number of shares, basic and diluted	22,228,723	6,878,782

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	For the Three Months Ended March 31, 2021					
	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME (LOSS)	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance at December 31, 2020	20,577,123	$ 20,577	$ 116,216,966	$ —	$ (88,037,759)	$ 28,199,784
Issuance of common stock, net of fees	2,218,874	2,219	12,576,307	—	—	12,578,526
Stock-based compensation	—	—	752,962	—	—	752,962
Stock options exercised	1,933	2	1,434	—	—	1,436
Net loss	—	—	—	—	(5,151,923)	(5,151,923)
Balance at March 31, 2021	22,797,930	$ 22,798	$ 129,547,669	$ —	$ (93,189,682)	$ 36,380,785

	For the Three Months Ended March 31, 2020					
	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME (LOSS)	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
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

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three months ended March 31,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (5,151,923)	$ (2,084,818)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	50,137	32,975
Stock-based compensation	752,962	287,807
Change in assets - (increase) decrease:		
Receivables	—	(30,659)
Prepaid expenses and other current assets	274,851	137,407
Other assets	—	12,228
Change in liabilities - increase (decrease):		
Accounts payable and accrued expenses	744,603	426,904
NET CASH USED IN OPERATING ACTIVITIES	(3,329,370)	(1,218,156)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	—	(6,130,193)
Proceeds from sales and maturities of marketable securities	—	12,117,000
Purchases of property and equipment	(36,912)	—
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	(36,912)	5,986,807
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	12,578,526	4,460,210
Proceeds from exercise of warrants	—	89,292
Proceeds from stock options	1,436	—
NET CASH PROVIDED BY FINANCING ACTIVITIES	12,579,962	4,549,502
NET INCREASE IN CASH AND CASH EQUIVALENTS	9,213,680	9,318,153
Cash and cash equivalents balance at beginning of period	32,665,874	3,899,328
Cash and cash equivalents balance at end of period	$ 41,879,554	$ 13,217,481
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" or "we"), is a biotechnology company focused on the development of transformative cell- and exosome-based therapeutics for the treatment and prevention of a broad spectrum 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 multiple active drug and vaccine 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 15, 2021, from which the December 31, 2020 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, 2021.

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 a former collaboration partner, a loan award and a grant from the California Institute for Regenerative Medicine ("CIRM").

Cash and cash equivalents as of March 31, 2021 were approximately $41.9 million, compared to approximately $32.7 million as of December 31, 2020. 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").

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

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 research and development activities, clinical trials and preclinical 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.

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 assumptions used to estimate stock-based compensation expense. Management uses its historical records and knowledge of its business in making these estimates. Accordingly, actual results may differ from these estimates.

Cash and Cash Equivalents

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

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 $49,054 and $31,893 for the three months ended March 31, 2021 and 2020, respectively.

Property and equipment, net consisted of the following:

	March 31, 2021	December 31, 2020
Furniture and fixtures	$ 48,676	$ 48,676
Laboratory equipment	1,510,620	1,473,708
Leasehold improvements	47,043	47,043
	1,606,339	1,569,427
Less accumulated depreciation	(767,634)	(718,580)
Property and equipment, net	$ 838,705	$ 850,847

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 $1,083 for each of the three months ended March 31, 2021 and 2020. A summary of future amortization expense as of March 31, 2021 is as follows:

Years ended	Amortization Expense
2021 (3 months)	$ 1,083

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 three months ended March 31, 2021 and 2020.

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 assets. 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

The company applies ASU 606, *Revenue from Contracts with Customers*, for all contracts.

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 a 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.

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 $3.3 million and $1.2 million for the three months ended March 31, 2021 and 2020, 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 $5.2 million and $2.1 million for the three months ended March 31, 2021 and 2020, respectively. The Company's other comprehensive income (loss) is related to a net unrealized gain (loss) on marketable securities. For the three months ended March 31, 2021 and 2020, the Company's other comprehensive income (loss) was zero and $757, respectively.

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 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 preclinical 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 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 delays 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, all of 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 and comprehensive loss. 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.

Basic and Diluted Loss per Share

The Company reports earnings per share in accordance with FASB 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 months ended March 31, 2021 and 2020, warrants and options to purchase 3,793,237 and 5,307,944 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 months ended March 31, 2021 and 2020.

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.

Carrying amounts reported in the balance sheet of cash and cash equivalents, 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.

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.

In October 2019, the FASB issued ASU 2019-12, which affects general principles within Topic 740, *Income Taxes*. The amendments of ASU 2019-12 are meant to simplify and reduce the cost of accounting for income taxes. For public business entities, the amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company adopted ASU 2019-12 in the first quarter of 2021. The adoption of this update did not have a material impact on the Company's financial statements and footnote disclosures.

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

In the second quarter of 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. The Loan was approved and Capricor received the Loan proceeds, which we used for covered payroll costs 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"), had a two-year term, was set to mature on April 29, 2022, and was to bear interest at a rate of 1.0% per annum. Monthly principal and interest payments, less the amount of any potential forgiveness, were to commence 10 months after the end of the covered period for the borrower's loan forgiveness (either 8 or 24 weeks). Loan payments were to be deferred for borrowers who apply for loan forgiveness until SBA remits the borrower's loan forgiveness amount to the lender. 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 provided for customary events of default, including, among others, those relating to failure to make payment, bankruptcy, breaches of representations and material adverse events. Capricor had the right to prepay the principal of the Loan at any time without incurring any prepayment charges.

The Company submitted a loan forgiveness application to CNB in the first quarter of 2021. The Loan was forgiven by the SBA in April 2021. The Company recognized a gain on forgiveness in April 2021.

3. STOCKHOLDER'S EQUITY

ATM Programs and Other Offerings

The Company has established multiple "at-the-market", or ATM, programs pursuant to a Common Stock Sales Agreement with Wainwright by which Wainwright sold and may continue to sell our 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 "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.

August 2019 ATM Program

On August 29, 2019, the Company initiated the August 2019 ATM Program. From August 29, 2019 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 May 13, 2021, the Company has sold an aggregate of 6,027,852 shares of common stock under the May 2020 ATM Program at an average price of approximately $6.15 per share for gross proceeds of approximately $37.1 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 $1.2 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 31, 2021, 61,173 December 2019 Common Warrants remained outstanding under the December 2019 Financing.

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.

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. As of March 31, 2021, 65,000 March 2020 Placement Agent Warrants remained outstanding under the March 2020 Warrant Inducement.

Outstanding Shares

At March 31, 2021, the Company had 22,797,930 shares of common stock issued and outstanding.

4. STOCK AWARDS, WARRANTS AND OPTIONS

Warrants

The following table summarizes all warrant activity for the three months ended March 31, 2021:

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2020	126,173	$ 1.32
Granted	—	—
Exercised	—	—
Outstanding at March 31, 2021	126,173	$ 1.32

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

Type	Grant Date	Warrants Outstanding March 31, 2021	Warrants Outstanding December 31, 2020	Exercise Price per Share	Expiration Date
Common Warrants	12/19/2019	61,173	61,173	$ 1.10	12/19/2024
Common Warrants	3/27/2020	65,000	65,000	$ 1.5313	3/27/2025
		126,173	**126,173**		

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"). In April 2021, the Board also approved the 2021 Equity Incentive Plan (the "2021 Plan"), however the 2021 Plan will not become effective unless and until it is approved by the shareholders of the Company. The Company is seeking stockholder approval for the 2021 Plan at its 2021 annual stockholders' meeting.

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 to104,547 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. For the fiscal year beginning on January 1, 2021, the number of shares added was equal to 823,084 shares.

As of March 31, 2021, 515,647 options remain available for issuance under the respective stock option plans.

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. Stock options are granted with an exercise price equal to the closing price of the Company's common stock on the date of grant, and generally vest over a period of one to four years. The term of stock options granted under each of the plans cannot exceed ten years.

The estimated weighted average fair value of the options granted during the three months ended March 31, 2021 and 2020 were approximately $3.26 and $1.03 per share, respectively.

The Company estimates the fair value of each option award using the Black-Scholes option-pricing model. The Company used the following assumptions to estimate the fair value of stock options issued in the three months ended March 31, 2021 and 2020:

	March 31, 2021	March 31, 2020
Expected volatility	124 %	104% - 107 %
Expected term	6 years	5 - 6 years
Dividend yield	0 %	0 %
Risk-free interest rates	0.5 %	0.9 - 1.5 %

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

	Three months ended March 31,	
	2021	2020
General and administrative	$ 633,120	$ 247,497
Research and development	119,842	40,310
Total	$ 752,962	$ 287,807

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.

The following is a schedule summarizing employee and non-employee stock option activity for the three months ended March 31, 2021:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2020	2,361,873	$ 1.89	$ 4,236,737
Granted	1,333,824	3.74	
Exercised	(2,133)	1.39	$ 10,928
Expired/Cancelled	(26,500)	4.18	
Outstanding at March 31, 2021	3,667,064	$ 2.54	$ 8,076,356
Exercisable at March 31, 2021	1,075,207	$ 1.65	$ 3,304,023

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 March 31, 2021, the Company maintained approximately $41.5 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.

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 March 31, 2021, 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, commercial-ready process to manufacture CAP-2003. Under the terms of the award, disbursements were made to Capricor over a period of approximately four 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. The Company utilized approximately $2.3 million under the terms of the award. We are currently completing all close-out documentation associated with this 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. Effective January 1, 2021, we entered into a month-to-month lease amendment with the Bubble Real Estate. The lease is terminable by either party upon 90 days' written notice to the other party. The monthly rental payment is $13,073.

Capricor leases facilities from Cedars-Sinai Medical Center ("CSMC"), a related party (see Note 9 – "Related Party Transactions"), 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. In July 2020, Capricor exercised its option to extend the term of the Facilities Lease for an additional 12-month period through July 31, 2021 with a monthly lease payment of $15,805. The Company has a further option to extend the Facilities Lease with respect to a portion of the leased premises through July 31, 2022 and a monthly lease payment of $10,707. At this time, we are actively evaluating new facilities for our research and development activities or the possible extension of our current lease.

Included within the table below, future minimum rental payments to related parties totaled $63,220. A summary of future minimum rental payments required under operating leases as of March 31, 2021 is as follows:

Years ended	Operating Leases
2021 (4 months)	$ 63,220

Expenses incurred under operating leases to unrelated parties for the three months ended March 31, 2021 and 2020 were $39,219 and $48,687, respectively. Expenses incurred under operating leases to related parties for each of the three months ended March 31, 2021 and 2020 were $47,415.

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

During 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.

Other Funding Commitments

The Company is a party to various agreements, principally relating to licensed technology, that require future payments relating to milestones that may be met in subsequent periods or royalties on future sales of specific products (see Note 8 – "License Agreements").

Additionally, the Company is a party to various agreements with contract research organizations and contract manufacturers that generally provide for termination upon notice, with the exact amounts owed in the event of termination to be based on the timing of termination and the terms of the agreement.

Employee Severances

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, in the event of termination of their employment, subject to certain conditions. No liability has been recorded as of March 31, 2021.

8. LICENSE AGREEMENTS

Capricor's Technology - CAP-1002 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"), Johns Hopkins University ("JHU") and CSMC. Capricor has also entered into an exclusive license agreement for intellectual property rights related to exosomes with CSMC and a non-exclusive license agreement with JHU related to the imaging-based serology technology for COVID-19. 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.

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 Agreements

License Agreement for CDCs

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 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.

License Agreement for Serology Diagnostic

Capricor and JHU entered into a Nonexclusive License Agreement (the "JHU Serology License Agreement"), effective January 6, 2021, which provides for the grant of a non-exclusive, world-wide, non-royalty-bearing license by JHU to Capricor to develop and commercialize licensed products under the licensed patent rights for COVID-19.

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.

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, August 5, 2016, December 26, 2017 and June 20, 2018, Capricor and CSMC entered into a number of amendments to the Amended CSMC License Agreement, pursuant to which the parties agreed to add and delete certain patent applications from the list of scheduled patents. Capricor reimbursed CSMC for certain attorneys' fees and filing fees incurred in connection with the 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, June 10, 2015, August 5, 2016, December 26, 2017, June 20, 2018, September 25, 2018, August 19, 2020, August 28, 2020, and March 19, 2021 Capricor and CSMC entered into a number of amendments to the Exosomes License Agreement. Collectively, these amendments added additional patent applications and patent families to the Exosomes License Agreement, added certain defined product development milestone payments, modified certain milestone deadlines, and added certain performance milestones with respect to product candidates covered by certain future patent rights in order to maintain an exclusive license to those future patent rights; failure to meet those milestones would cause CSMC to have the right to convert the license from exclusive to non-exclusive or co-exclusive, or to terminate the license, subject to Capricor's right to license such patent rights for internal research purposes on a non-exclusive basis. These amendments also obligated Capricor to reimburse CSMC for certain attorneys' fees and filing fees in connection with the additional patent applications and patent families.

Sponsored Research Agreement with Johns Hopkins University

On April 1, 2020 we entered into a Sponsored Research Agreement (the "SRA"), with JHU 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 certain 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 (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 was on a month-to-month basis and was terminated effective September 1, 2020. For the three months periods ended March 31, 2021 and 2020, Capricor recognized zero and $7,500, respectively, in sublease income from the related party. Sublease income is recorded as a reduction to general and administrative expenses.

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

As of March 31, 2021 and December 31, 2020, the Company had accounts payable and accrued expenses to related parties totaling $321,334 and $8,972, respectively. CSMC accounts for all of the total accounts payable and accrued expenses to related parties as of each of March 31, 2021 and December 31, 2020, respectively. CSMC expenses relate to research and development costs, clinical trial costs, license and patent fees, and facilities rent. During the three months ended March 31, 2021 and 2020, the Company paid CSMC approximately $57,700 and $68,900, 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. The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells" or ALPHA. In both studies, Capricor is providing 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 three months ended March 31, 2021 and 2020, the Company recognized approximately $40,800 and $67,000, respectively, as revenue. As of March 31, 2021, and December 31, 2020, zero and approximately $56,000, respectively, is outstanding and recorded in prepaid expenses and other current assets. As of March 31, 2021, 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 each of the ALPHA and REGRESS trials has been delayed and as a result, purchases of additional doses of CAP-1002 have been delayed.

10. SUBSEQUENT EVENTS

JHU License Agreement for Exosome-based Vaccines and Therapeutics

Capricor and JHU entered into an Exclusive License Agreement (the "JHU Exosome License Agreement") effective April 28, 2021 for its co-owned interest in certain intellectual property rights related to exosome-mRNA vaccines and therapeutics. The JHU Exosome License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by JHU 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.

Pursuant to the JHU Exosome License Agreement, JHU was paid an upfront license fee of $10,000 and Capricor has agreed to reimburse JHU for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor is required to meet certain development milestones for which a milestone payment fee shall be due and is obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a double-digit percentage

of any non-royalty consideration received from any sublicenses. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to pay royalties on one or more third party patents as a requirement to make or sell a licensed product. In addition, Capricor will, beginning with the third year of the JHU Exosome License Agreement, be obligated to pay JHU a minimum annual royalty which is non-refundable but will be credited against royalties incurred by Capricor for the year in which the minimum annual royalty becomes due.

The JHU Exosome License Agreement will, unless sooner terminated, continue in each country until the date of expiration of the last to expire patent included within the patent rights in that country, or if no patents issue, then for 20 years. The JHU Exosome License Agreement may be terminated by Capricor upon 90 days' written notice in its discretion and with 60 days' notice with respect to any particular patent or application or as to any particular licensed product. The JHU Exosome License Agreement may also be terminated by either party if it fails to perform or otherwise breaches any of its obligations and fails to cure such breach within a 60-day cure period commencing upon notice. A material breach by Capricor may include (a) a delinquency with respect to payment or reporting; (b) the failure by Capricor to timely achieve a specified milestone or otherwise failing to diligently develop, commercialize, and sell licensed products throughout the term of the JHU Exosome License Agreement; (c) non-compliance with record keeping or audit obligations; (d) voluntary bankruptcy or insolvency of Capricor; and (e) non-compliance with Capricor's insurance obligations.

Additional Sales Under May 2020 ATM Program

Subsequent to March 31, 2021 and through May 13, 2021, the Company sold an aggregate of 80,000 common shares under the May 2020 ATM Program at an average price of approximately $5.11 per common share for gross proceeds of approximately $409,000. 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 $12,750.

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 development of transformative cell- and exosome-based therapeutics for the treatment and prevention of a broad spectrum of diseases.

Cell Therapy (CAP-1002) Program

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 Duchenne muscular dystrophy, or DMD. The 12-month top-line data showed improvements in multiple measures of upper limb, cardiac and respiratory functions. Following receipt of the 12-month data, we 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 License Application, or BLA, for CAP-1002 in DMD. The FDA has continued to encourage us to conduct a Phase III study; at this time, however, we are still discussing the pathway forward for this program with the FDA and have not initiated a Phase III study. We recently submitted a new data package to the FDA for which we requested for an additional Type B meeting to further discuss our path towards registration for this product candidate. Additionally, we are actively seeking partners for this program.

CAP-1002 - COVID-19 Program

In 2020, under an Expanded Access (or Compassionate Use) program, seven patients hospitalized with severe COVID-19 (also referred to sometimes as SARS-CoV-2) symptoms, six of whom were ventilated, were treated with CAP-1002. Four of the seven patients were fully discharged and three died between one- and two-months post-treatment. Previously published data has shown that COVID-19 patients on ventilators experience higher 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 was associated with 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 demonstrated due to the small sample size, the fact that seven patients were contemporaneously on other experimental medications, and the lack of an established control group, among other factors.

In August 2020, we received FDA acceptance of our IND application for a clinical study of CAP-1002 in patients with severe or critical COVID-19. The INSPIRE trial is a Phase II, randomized, double-blind, placebo-controlled study that is enrolling up to 60 patients from several trial sites in the United States. The study is enrolling patients who have a diagnosis of SARS-CoV-2 and require supplemental oxygen. Various outcome measures will be analyzed including, but not limited to, safety, cytokine biomarkers, all-cause mortality, cardiac biomarkers and hospitalization length. We expect to have top-line data available in the third quarter of 2021. Following receipt of this data, we will discuss next steps for the program with FDA. Additionally, we are actively seeking partners for this program.

Exosomes Program

Exosomes-Based Vaccine

We are currently engaged in the development of a vaccine candidate for the potential prevention of COVID-19. The vaccine candidate is a multivalent exosome-mRNA vaccine which is designed to elicit a protective, long-lasting immune response to SARS-CoV-2 by targeting multiple structural proteins of the virus. In December 2020, we announced positive preclinical data from a study using our exosome-mRNA vaccine approach. We recently met with the FDA in a pre-IND meeting and are planning on filing an IND by the third quarter of 2021, subject to regulatory approval, for this vaccine for SARS-CoV-2. We have also been investigating an exosomal antigen vaccine which is a vesicle-based, nucleic acid-free formulation carrying multiple structural proteins of SARS-CoV-2.

Exosome-Based Therapeutics

We are also developing our exosomes platform technology as a next-generation therapeutic platform. Our current focus is on the development of exosomes loaded with nucleic acids, including mRNA, to treat a variety of diseases. mRNA medicines are not small molecules, like traditional pharmaceutical drugs and they are not traditional biologics (such as recombinant proteins and monoclonal antibodies) – which were the origins of the biotech industry. Instead, mRNA medicines are sets of instructions. And these instructions direct cells in the body to make all the proteins required for life as well as to prevent or fight disease.

Our platform builds on advances in fundamental RNA science, targeting technology and manufacturing, providing us the opportunity to build a broad pipeline of potential new therapeutic candidates. At this time, we are developing therapeutics and vaccines for infectious diseases, monogenic diseases and other indications. We recently entered into an Exclusive License Agreement with Johns Hopkins University for its co-owned interest in certain intellectual property rights related to exosome-mRNA vaccines and therapeutics.

CDC-Derived Exosomes (CAP-2003)

In April 2020, we filed an IND with the FDA to investigate the use of CAP-2003 in patients with DMD. At this time, the FDA has requested more information related to manufacturing and we are evaluating the next steps for this program. We need to submit further information to FDA to support the potential acceptance of this IND.

Additionally, in July 2018, we entered into a Cooperative Research and Development Agreement with the U.S. Army Institute of Surgical Research, or USAISR, pursuant to which we agreed to cooperate in research and development on the evaluation of our CAP-2003 for the treatment of trauma related injuries and conditions.

Aspects of our exosomes pipeline have been supported through collaborations and alliances. We have entered into a Sponsored Research Agreement with Johns Hopkins University, or JHU, pursuant to which researchers in the lab of Dr. Stephen Gould will perform certain research activities in connection with our exosomes program and the further development of the platform. Additional collaborations include the Department of Defense, the National Institutes of Health and Cedars-Sinai Medical Center, or CSMC.

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 cell therapy 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 over 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 DMD, and investigating their effects on skeletal and cardiac function. Preclinical 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 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 and 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

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. Our preclinical data has shown that CDCs mediate most of their therapeutic activities through the secretion of extracellular vesicles.

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, preclinical 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.

Background on Duchenne Muscular Dystrophy

DMD is a rare form of muscular dystrophy which results in muscle degeneration and premature death. DMD affects approximately 1 in 3,600 male infants worldwide, and it is estimated that approximately 15,000 to 20,000 boys and young men are living with the disease in the United States. DMD results from the lack of functional dystrophin protein caused by a gene mutation. The lack of dystrophin, an important structural component of muscle cells, causes them to have increased susceptibility to damage and to progressively die. Additionally, the absence of dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. In DMD patients, heart muscle cells progressively die and are replaced with scar tissue. This cardiomyopathy eventually leads to heart failure, which is currently the leading cause of death among those with DMD.

Patients with DMD experience progressive muscle weakness and degeneration starting at an early age. Generally, a loss of ambulation occurs after the first decade of life and eventually the patients suffer respiratory and cardiac failure. Their lifespan is abbreviated and averages less than three decades. The annual cost of care for patients with DMD is very high and increases with disease progression. We therefore believe that DMD represents a significant market opportunity for our product candidate, CAP-1002.

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 preclinical models of DMD, we believe that CAP-1002 has the potential to decrease inflammation and slow 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 preclinical 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 2019 and we reported top-line 12-month results in May 2020. 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, our ability to partner with another company to advance the development of CAP-1002 for DMD, and/or our ability to manufacture the product through a contract manufacturer, as well as other factors, some of which are not known at this time. Further, we have submitted a proposed Phase III protocol to the FDA. The size of the proposed Phase III trial is estimated to be approximately 60 patients and in our continuing discussions, FDA has indicated its acceptance of this potential study design.

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 assessed the mid-level dimension of the PUL which evaluates one's ability to use muscles extending from the elbow to the hand, which muscles 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 a pre-specified interim analysis of 6-month data from the HOPE-2 trial, which showed meaningful results across several independent clinical measures.

In May 2020, we reported top-line 12-month results. The data showed improvements in upper limb, cardiac and respiratory functions 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 significant 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. In HOPE-2 treatment with CAP-1002 was associated with 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.

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 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 Type B meeting with the FDA in 2020, we focused on the 12-month results from the HOPE-2 trial and discussed next steps and a pathway to approval of a BLA, for CAP-1002 in DMD. The FDA has continued to encourage us to conduct a Phase III study; at this time, however, we are still discussing the pathway forward for this program with the FDA and have not initiated a Phase III study.

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-Duchenne 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 incidences 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 in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and that affects fewer than 200,000 individuals 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. 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, modify, reverse, or cure a serious or life-threatening disease or 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 fast track or 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 SARS-CoV-2

Within the framework of SARS-CoV-2 pathogenesis, multiple pathways known to be CAP-1002 sensitive may serve as therapeutic targets. These targets include pro-inflammatory pathways (TNF-α, interferon γ, IL-1, and IL-6) and anti-inflammatory pathways (regulatory T cells and IL-10) that have been explored with CAP-1002 in preclinical models of myocardial ischemia, myocarditis, heart failure, Duchenne muscular dystrophy and pulmonary hypertension. Given that CAP-1002 polarizes macrophages to an anti-inflammatory (healing) immunomodulatory phenotype, CAP-1002 may subsequently attenuate cytokine storm associated with SARS-CoV-2. Furthermore, as CAP-1002 directly targets cardiac dysfunction, CAP-1002 potentially may also be an important tool in the treatment of the cardiac complications of SARS-CoV-2. We are currently conducting the INSPIRE Phase II clinical trial in patients with a diagnosis of SARS-CoV-2.

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 (the ALLSTAR trial). 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. 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, or the REGRESS trial. Dr. Eduardo Marbán is the named principal investigator under the study. The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells, or the ALPHA trial. 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 each of the ALPHA and REGRESS trials has been delayed and as a result, purchases of additional doses of CAP-1002 have been delayed.

Exosomes Program

Our exosomes program consists of exosome-based vaccines, engineered exosomes and exosomes derived from CDCs (CAP-2003), all of which are in various stages of development. We have explored the use of our CDC-exosomes in preclinical 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 has the ability to deliver 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 monogenic diseases.

In conjunction with these expansion efforts, we have entered into a Sponsored Research Agreement with JHU pursuant to which researchers in the lab of Dr. Stephen Gould will perform certain research activities in connection with our exosomes program and the further development of the platform.

Exosomes-Based Vaccine Platform

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 currently engaged in the development of a vaccine candidate for the potential prevention of COVID-19. The vaccine candidate is a multivalent exosome-mRNA vaccine which is designed to elicit a protective, long-lasting immune response to SARS-CoV-2 by targeting multiple structural proteins of the virus. In December 2020, we announced positive preclinical data from a study using our exosome-mRNA vaccine approach. We recently met with the FDA in a pre-IND meeting and are planning on filing an IND by the third quarter of 2021, subject to regulatory approval, for this vaccine for SARS-CoV-2. We have also been investigating an exosomal antigen vaccine which is a vesicle-based, nucleic acid-free formulation carrying multiple structural proteins of SARS-CoV-2. We continue to assess this technology for potential uses within infectious diseases and potentially other uses.

Furthermore, we recently entered into a non-exclusive license to intellectual property, know-how and data with JHU related to a new imaging-based serology test platform for COVID-19. This platform, which is amenable to a vast array of serology applications, has been applied to the analysis of patient antibodies to multiple SARS-CoV-2 proteins, including spike, nucleocapsid, and membrane. The development of this companion diagnostic allows us to accurately evaluate the effects of our vaccines and therapeutics and we intend to explore the potential for partnership opportunities for this technology.

Engineered Exosomes Platform

Building upon the natural ability of exosomes for intercellular communication, we are focused on engineering exosomes to load them with different macromolecules. We are actively developing an engineered exosomes platform for the delivery of nucleic acids (including mRNA) for a variety of different diseases. In collaboration with researchers at JHU, we recently published data demonstrating exosome-mediated delivery of mRNAs with enhanced expression and lower toxicity compared to lipid nanoparticles. Additionally, we showed functional enzyme expression and real-time

imaging of mRNA expression in live animals. Building on this platform, we have promising data for enhanced targeting of exosomes. Our plan is to actively develop this platform for a broad spectrum of diseases.

CDC-Exosomes (CAP-2003)

We have promising preclinical 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 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 one of the leading causes 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. At this time, the FDA has requested more information related to manufacturing and we are evaluating the next steps for this program. We need to submit further information to FDA to support the potential acceptance 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 our exosome technologies. As we proceed with the clinical development of CAP-1002, and as we further develop our exosome technologies, 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 recent major sources of working capital have been primarily proceeds from private and public equity sales of securities. While we pursue our preclinical and clinical programs, we continue to explore potential partnerships for the development of 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 preclinical, 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 March 31, 2021 and 2020 was approximately zero and $0.1 million, respectively. Grant income for the first quarter of 2020 related to the DoD Grant Award. The decrease relates to the timing of the award as the DoD Grant Award which expired in September 2020.

Miscellaneous Income. Miscellaneous income for the three months ended March 31, 2021 and 2020 was approximately $41,000 and $67,000, 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 to delays in the clinical trials sponsored by CSMC caused by the COVID-19 pandemic.

Operating Expenses

General and Administrative Expenses. G&A expenses for the three months ended March 31, 2021 and 2020 were approximately $1.9 million and $1.1 million, respectively. The increase of approximately $0.8 million in G&A expenses in the first quarter of 2021 compared to the same period of 2020 is primarily attributable to an increase of approximately $0.4 million in stock-based compensation expense. Furthermore, there was an increase of approximately $0.1 million attributable to an increase in salaries, approximately $0.1 million related to insurance expenses, approximately $0.1 million for investor relations expenses, and approximately $0.1 million associated to legal expenses and other general expenses.

Research and Development Expenses. R&D expenses for the three months ended March 31, 2021 and 2020 were approximately $3.3 million and $1.2 million, respectively. The increase of approximately $2.1 million in R&D expenses in the first quarter of 2021 compared to the same period of 2020 is primarily due to the timing of clinical development activities of CAP-1002 (DMD and COVID-19 clinical trials). These activities resulted in a net increase of approximately $0.6 million. Furthermore, for the quarter ended March 31, 2021, there was an increase of approximately $0.7 million in research and development expenses primarily related to our exosomes program and an increase of approximately $0.7 million in technology transfer and manufacturing related activities of CAP-1002. Lastly, there was an increase of approximately $0.1 million in stock-based compensation expenses allocable to R&D for the quarter ended March 31, 2021 as compared to the quarter ended March 31, 2020.

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 2021 on the development of CAP-1002 for DMD and COVID-19, which expenses are primarily related to clinical, regulatory and manufacturing-related expenses, including our technology transfer with Lonza Houston, Inc. These figures are largely dependent on the next steps in our DMD and COVID-19 programs, 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 $10.0 million to $12.0 million during 2021 on development expenses related to our exosomes program, which includes preclinical and manufacturing related expenses for these technologies. Our expenses for this program are primarily related to our exosome-mRNA vaccine, which may include expenses related conducting a clinical trial, subject to regulatory approval, as well as expenses focused on the expansion of our engineered exosomes platform including the planned expansion of our research and development team. Furthermore, we have expenses in connection with our Sponsored Research Agreement with Johns Hopkins University for further research related to our exosome platform technology.

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;
- the costs, requirements and timing of, and the ability to secure, regulatory approvals; and
- additional delays caused by the COVID-19 pandemic.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of March 31, 2021 and December 31, 2020 and our net increase in cash and cash equivalents for the three months ended March 31, 2021 and 2020, 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	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 41,880	$ 32,666
Working capital	$ 38,864	$ 30,706
Stockholders' equity	$ 36,381	$ 28,200

	Three months ended March 31,	
Cash flow data	2021	2020
Cash provided by (used in):		
Operating activities	$ (3,329)	$ (1,218)
Investing activities	(37)	5,987
Financing activities	12,580	4,549
Net increase in cash and cash equivalents	$ 9,214	$ 9,318

Our total cash and cash equivalents as of March 31, 2021 was approximately $41.9 million compared to approximately $32.7 million as of December 31, 2020. The increase in cash and cash equivalents from December 31, 2020 to March 31, 2021 is primarily due to net proceeds related to financing activities of approximately $12.6 million and a net loss of approximately $5.2 million for the three months ended March 31, 2021. As of March 31, 2021, we had approximately $7.2 million in total liabilities and approximately $38.9 million in net working capital.

Cash used in operating activities was approximately $3.3 million and $1.2 million for the three months ended March 31, 2021 and 2020, respectively. The difference of approximately $2.1 million in cash from operating activities is primarily due to an increase of approximately $3.1 million in net loss for the three months ended March 31, 2021 as compared to the same period in 2020. Furthermore, there was an increase of approximately $0.3 million in accounts payable and accrued liabilities and an increase of approximately $0.5 million in stock-based compensation for the three months ended March 31, 2021 as compared to the same period in 2020. 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 preclinical 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 used in investing activities of approximately $37,000 and provided by investing activities of $6.0 million for the three months ended March 31, 2021 and 2020, respectively. The decrease in cash from investing activities for the three months ended March 31, 2021 as compared to the same period of 2020 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 $12.6 million and $4.5 million for the three months ended March 31, 2021 and 2020, respectively. The increase in cash provided by financing activities for the three months ended March 31, 2021 is primarily due to the approximate $12.6 million in net proceeds received from the May 2020 ATM Program and exercise of common warrants.

From inception through March 31, 2021, we financed our operations primarily through private and public sales of our equity securities, NIH and DoD grants, a payment from a former collaboration partner, 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. At this time, we believe our cash resources are sufficient to fund our operations for at least the next twelve months. 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 preclinical 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 May 13, 2021, the Company has sold an aggregate of 6,027,852 shares of common stock under the May 2020 ATM Program at an average price of approximately $6.15 per share for gross proceeds of approximately $37.1 million. Approximately $2.9 million of common stock may still be sold pursuant to the May 2020 ATM Program. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of Wainwright and legal fees in the aggregate amount of approximately $1.2 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 were not 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 warrants, 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. As of March 31, 2021, 65,000 March 2020 Placement Agent Warrants remained outstanding under the March 2020 Warrant Inducement.

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. As of March 31, 2021, 61,173 December 2019 Common Warrants remained outstanding under the December 2019 Financing.

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 provided that Wainwright was 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 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. At the expiration of the August 2019 ATM Program, the Company had 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.

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.

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 March 31, 2021, 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, commercial-ready process to manufacture CAP-2003. Under the terms of the award, disbursements were made to Capricor over a period of approximately four 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. The Company utilized approximately $2.3 million under the terms of the award. We are currently completing all close-out documentation associated with this 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 March 31, 2021.

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

The Company applies ASU 606, *Revenue from Contracts with Customers*, for all contracts.

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. In June, 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. 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 preclinical, 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, or the 2020 Plan. In April 2021, the Board also approved the 2021 Equity Incentive Plan (the "2021 Plan"), however the 2021 Plan will not become effective unless and until it is approved by the shareholders of the Company. The Company is seeking stockholder approval for the 2021 Plan at its 2021 annual stockholders' meeting.

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. 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.

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.

In October 2019, the FASB issued ASU 2019-12, which affects general principles within Topic 740, Income Taxes. The amendments of ASU 2019-12 are meant to simplify and reduce the cost of accounting for income taxes. For public business entities, the amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company adopted ASU 2019-12 in the first quarter of 2021. The adoption of this update did not have a material impact on the Company's financial statements and footnote disclosures.

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 March 31, 2021, the fair value of our cash and cash equivalents was approximately $41.9 million. Additionally, as of March 31, 2021, Capricor's investment 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 March 31, 2021 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, 2020, as filed with the SEC on March 15, 2021, 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. 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, 2020, as filed with the SEC on March 15, 2021.

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	Amended and Restated Bylaws 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 August 25, 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 March 31, 2021 formatted in eXtensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of March 31, 2021 and December 31, 2020, (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: May 14, 2021

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

Date: May 14, 2021

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: May 14, 2021

/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: May 14, 2021

/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 March 31, 2021 (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: May 14, 2021

/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 March 31, 2021 (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: May 14, 2021

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