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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, 2024**

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.)**

10865 Road to the Cure, Suite 150, San Diego, California 92121
(Address of principal executive offices including zip code)

(858) 727-1755
(Registrant's telephone number, including area code)

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

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

As of May 13, 2024, there were 31,811,470 shares of the registrant's common stock, par value $0.001 per share, issued and outstanding.

INDEX TO QUARTERLY REPORT ON FORM 10-Q

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, Biologics License Application ("BLA"), and other regulatory submissions;
- regulatory developments involving products and our facilities, 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 Regenerative Medicine Advanced Therapy ("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 procure materials necessary for the manufacture of our product candidates;
- our ability to protect our patents and other intellectual property;
- 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, future reimbursement prices for any commercial products, 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, 2024 (unaudited)	December 31, 2023
CURRENT ASSETS		
Cash and cash equivalents	$ 6,214,647	$ 14,694,857
Marketable securities	33,702,431	24,792,846
Receivables	369,000	10,371,993
Prepaid expenses and other current assets	1,125,844	995,776
TOTAL CURRENT ASSETS	41,411,922	50,855,472
PROPERTY AND EQUIPMENT, net	5,893,552	5,560,641
OTHER ASSETS		
Lease right-of-use assets, net	1,845,246	2,050,042
Other assets	293,722	268,172
TOTAL ASSETS	$ 49,444,442	$ 58,734,327
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 6,248,657	$ 6,250,241
Lease liabilities, current	771,506	749,112
Deferred revenue, current	19,363,589	24,270,465
TOTAL CURRENT LIABILITIES	26,383,752	31,269,818
LONG-TERM LIABILITIES		
CIRM liability	3,376,259	3,376,259
Lease liabilities, net of current	1,249,493	1,486,783
TOTAL LONG-TERM LIABILITIES	4,625,752	4,863,042
TOTAL LIABILITIES	31,009,504	36,132,860
COMMITMENTS AND CONTINGENCIES (NOTE 6)		
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, 31,600,183 and 31,148,320 shares issued and outstanding, respectively	31,600	31,148
Additional paid-in capital	187,257,063	181,701,859
Accumulated other comprehensive income	307,701	235,813
Accumulated deficit	(169,161,426)	(159,367,353)
TOTAL STOCKHOLDERS' EQUITY	18,434,938	22,601,467
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 49,444,442	$ 58,734,327

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,	
	2024	2023
REVENUE		
Revenue	$ 4,906,877	$ 2,986,696
TOTAL REVENUE	4,906,877	2,986,696
OPERATING EXPENSES		
Research and development	11,101,013	7,661,519
General and administrative	4,071,766	3,509,885
TOTAL OPERATING EXPENSES	15,172,779	11,171,404
LOSS FROM OPERATIONS	(10,265,902)	(8,184,708)
OTHER INCOME (EXPENSE)		
Investment income	471,829	416,442
TOTAL OTHER INCOME (EXPENSE)	471,829	416,442
NET LOSS	(9,794,073)	(7,768,266)
OTHER COMPREHENSIVE INCOME (LOSS)		
Net unrealized gain (loss) on marketable securities	71,888	(10,258)
COMPREHENSIVE LOSS	$ (9,722,185)	$ (7,778,524)
Net loss per share, basic and diluted	$ (0.31)	$ (0.31)
Weighted average number of shares, basic and diluted	31,354,629	25,247,354

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, 2024					
	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance at December 31, 2023	31,148,320	$ 31,148	$ 181,701,859	$ 235,813	$ (159,367,353)	$ 22,601,467
Issuance of common stock, net of fees	447,221	447	2,289,797	—	—	2,290,244
Stock-based compensation	—	—	3,265,412	—	—	3,265,412
Stock options exercised	4,642	5	(5)	—	—	—
Unrealized loss on marketable securities	—	—	—	71,888	—	71,888
Net loss	—	—	—	—	(9,794,073)	(9,794,073)
Balance at March 31, 2024	31,600,183	$ 31,600	$ 187,257,063	$ 307,701	$ (169,161,426)	$ 18,434,938

	For the Three Months Ended March 31, 2023					
	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance at December 31, 2022	25,241,402	$ 25,241	$ 148,735,420	$ 105,244	$ (137,079,811)	$ 11,786,094
Stock-based compensation	—	—	2,194,784	—	—	2,194,784
Stock options exercised	13,752	14	3,881	—	—	3,895
Unrealized loss on marketable securities	—	—	—	(10,258)	—	(10,258)
Net loss	—	—	—	—	(7,768,266)	(7,768,266)
Balance at March 31, 2023	25,255,154	$ 25,255	$ 150,934,085	$ 94,986	$ (144,848,077)	$ 6,206,249

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,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (9,794,073)	$ (7,768,266)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	331,406	230,101
Stock-based compensation	3,265,412	2,194,784
Changes in lease liabilities	(10,100)	(6,452)
Changes in operating assets and liabilities:		
Receivables	10,002,993	—
Prepaid expenses and other current assets	(130,068)	44,800
Other assets	(25,550)	—
Accounts payable and accrued expenses	(1,584)	501,815
Deferred revenue	(4,906,876)	9,013,304
Net cash provided by (used in) operating activities	(1,268,440)	4,210,086
Cash flows from investing activities:		
Purchase of marketable securities	(33,210,697)	(34,803,580)
Proceeds from sales and maturities of marketable securities	24,373,000	32,045,000
Purchases of property and equipment	(608,588)	(347,690)
Payments for leasehold improvements	(55,729)	(105,425)
Net cash used in investing activities	(9,502,014)	(3,211,695)
Cash flows from financing activities:		
Net proceeds from sale of common stock	2,290,244	—
Proceeds from exercise of stock awards	—	3,895
Net cash provided by financing activities	2,290,244	3,895
Net increase (decrease) in cash and cash equivalents	(8,480,210)	1,002,286
Cash and cash equivalents balance at beginning of period	14,694,857	9,603,242
Cash and cash equivalents balance at end of period	$ 6,214,647	$ 10,605,528
Supplemental disclosures of cash flow information:		
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," the "Company," "we," "us" or "our"), is a clinical-stage biotechnology company focused on the development of transformative cell and exosome-based therapeutics for treating Duchenne muscular dystrophy ("DMD"), a rare form of muscular dystrophy which results in muscle degeneration and premature death, and other diseases with high unmet medical needs. Capricor, Inc. ("Capricor"), a wholly-owned subsidiary of Capricor Therapeutics, was founded in 2005 as a Delaware corporation. 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 therapeutic drug candidates in various stages of development.

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements for Capricor Therapeutics and its wholly-owned subsidiary have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") and with the instructions to Form 10-Q and, therefore, do not include all disclosures necessary for a complete presentation of financial position, results of operations and cash flows in conformity with U.S. GAAP. In the Company's opinion, all adjustments, consisting of normal and recurring adjustments, considered necessary for a fair presentation have been included. The accompanying financial information should be read in conjunction with the financial statements and the notes thereto in the Company's most recent Annual Report on Form 10-K, as filed with the Securities and Exchange Commission (the "SEC") on March 11, 2024, from which the December 31, 2023 consolidated balance sheet was derived. Interim results are not necessarily indicative of the results that may be expected for the year ending December 31, 2024.

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.

Reclassification

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

Liquidity and Going Concern

The Company has historically financed its research and development activities as well as operational expenses primarily from equity financings, government grants, and payments from distribution agreements and collaboration partners.

Cash, cash equivalents, and marketable securities as of March 31, 2024 were approximately $39.9 million, compared to approximately $39.5 million as of December 31, 2023. In the first quarter of 2024, the Company received our first milestone payment of $10.0 million from Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku"), which was triggered upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. Additionally, during the three months ended March 31, 2024, we sold 447,221 shares of common stock at an average price of approximately $5.33 per share pursuant to a Common Stock Sales Agreement in place with H.C. Wainwright & Co. LLC ("Wainwright") under our at-the-market offering, resulting in net proceeds of approximately $2.3 million (see Note 2 - "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 our research and development activities, clinical trials and preclinical studies, including the enrollment and progress of our ongoing HOPE-3 Phase 3 clinical trial of CAP-1002 in DMD;
- the timing and costs associated with the manufacturing of our product candidates, including the expansion of our manufacturing capacity to support the potential commercialization of CAP-1002 for DMD;
- the timing and costs associated with potential commercialization of our product candidates;
- the number and scope of our research programs, including the expansion of our exosomes program; 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, potential distribution and other partnering opportunities, and from government grants. The Company has incurred significant operating losses and negative cash flows from operations. Based on the Company's available cash resources and based upon the Company's projections for its operations, the Company does not have sufficient cash on hand to support current operations for at least the next twelve months from the date of filing this Quarterly Report on Form 10-Q. Therefore, there is a substantial doubt about the Company's ability to continue as a going concern.

The Company's plan to address its financial position may 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 from government grants. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The Company will require substantial additional capital to fund its operations. 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 portions of its clinical trial and research and development programs. To the extent the Company issues additional equity securities, its existing stockholders would experience substantial dilution.

Business Uncertainty Related to the Coronavirus

The COVID-19 pandemic presented substantial public health and economic challenges around the world. Our business operations and financial condition and results have been impacted to varying degrees.

In light of past 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 REGRESS and ALPHA trials as well as any potential equity and debt financings, the Company submitted for the Employee Retention Credit ("ERC"), a credit against certain payroll taxes allowed to an eligible employer for qualifying wages, which was established by the CARES Act. The Company has submitted $738,778 in ERC for applicable 2020 and 2021 periods, receiving $191,199 in 2021 and $191,463 in 2023. As of March 31, 2024, the Company has recorded a receivable for $366,551 for the remainder of funds for which we are still awaiting receipt.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. Management uses its historical records and knowledge of its business in making these estimates. Accordingly, actual results may differ from these estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of 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 presented as accumulated other comprehensive income (loss) as a separate component of stockholders' equity. As of March 31, 2024, marketable securities consist primarily of short-term United States treasuries.

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 $331,406 and $230,101 for the three months ended March 31, 2024 and 2023, respectively.

Property and equipment, net consisted of the following:

	March 31, 2024	December 31, 2023
Furniture and fixtures	$ 187,997	$ 187,997
Laboratory equipment	6,047,177	5,449,597
Leasehold improvements	2,184,832	2,129,102
	8,420,006	7,766,696
Less accumulated depreciation	(2,526,454)	(2,206,055)
Property and equipment, net	$ 5,893,552	$ 5,560,641

Leases

ASC Topic 842, *Leases* ("ASC 842"), requires lessees to recognize most leases on the balance sheet with a corresponding right-to-use asset ("ROU asset"). ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of fixed lease payments over the lease term. ROU assets are evaluated for impairment using the long-lived assets impairment guidance.

Leases will be classified as financing or operating, which will drive the expense recognition pattern. The Company elects to exclude short-term leases if and when the Company has them.

The Company leases office and laboratory space, all of which are operating leases (see Note 6 - "Commitments and Contingencies"). Most leases include the option to renew and the exercise of the renewal options is at the Company's sole discretion. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. In addition, the Company's lease agreements generally do not contain any residual value guarantees or restrictive covenants.

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.

For real estate leases, the Company has elected the practical expedient under ASC 842 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 adopted ASU 606, *Revenue for Contracts from Customers*, ("ASU 606"), which amended revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries (see Note 7 – "License and Distribution Agreements").

The revenue standard provides a five-step framework for recognizing revenue as control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that it determines are within the scope of the revenue standard, the Company performs the following five steps: (i) identify the contract; (ii) identify the performance obligations; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. At contract inception, the Company assesses whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation, or whether they are not distinct and are combined with other goods and services until a distinct bundle is identified. The Company then determines the transaction price, which typically includes upfront payments and any variable consideration that the Company determines is probable to not cause a significant reversal in the amount of cumulative revenue recognized when the uncertainty associated with the variable consideration is resolved. The Company then allocates the transaction price to each performance obligation and recognizes the associated revenue when, or as, each performance obligation is satisfied.

The Company's distribution agreements may entitle it to additional payments upon the achievement of milestones or shares of product revenue on sales. The milestones are generally categorized into three types: development milestones, regulatory milestones and sales-based milestones. The Company evaluates whether it is probable that the consideration associated with each milestone or shared revenue payments will not be subject to a significant reversal in the cumulative amount of revenue recognized. Amounts that meet this threshold are included in the transaction price using the most likely amount method, whereas amounts that do not meet this threshold are excluded from the transaction price until they meet this threshold. At the end of each subsequent reporting period, the Company re-evaluates the probability of a significant reversal of the cumulative revenue recognized for its milestones and royalties, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and net income (loss) in the Company's condensed consolidated statements of operation and comprehensive loss. Typically, milestone payments and shared revenue payments are achieved after the Company's performance obligations associated with the distribution agreements have been completed and after the customer has assumed responsibility for the commercialization program. Milestones or shared revenue payments achieved after the Company's performance obligations have been completed are recognized as revenue in the period the milestone or shared revenue payments were achieved. If a milestone payment is achieved during the performance period, the milestone payment would be recognized as revenue to the extent performance had been completed at that point, and the remaining balance would be recorded as deferred revenue.

The revenue standard requires the Company to assess whether a significant financing component exists in determining the transaction price. The Company performs this assessment at the onset of its distribution agreements. Typically, a significant financing component does not exist because the customer is paying for services in advance with an upfront payment. Additionally, future shared revenue payments are not substantially within the control of the Company or the customer.

Whenever the Company determines that goods or services promised in a contract should be accounted for as a combined performance obligation over time, the Company determines the period over which the performance obligations will be performed and revenue will be recognized. Revenue is recognized using either the proportional performance method or on a straight-line basis if efforts will be expended evenly over time. Percentage of completion of patient visits in clinical trials are used as the measure of performance. The Company feels this method of measurement to be the best depiction of the transfer of services and recognition of revenue. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations. If the Company determines that the performance obligation is satisfied over time, any upfront payment received is initially recorded as deferred revenue on its condensed consolidated balance sheets.

Certain judgments affect the application of the Company's revenue recognition policy. For example, the Company records short-term (less than one year) and long-term (over one year) deferred revenue based on its best estimate of when such revenue will be recognized. This estimate is based on the Company's current operating plan, and the Company may recognize a different amount of deferred revenue over the next 12-month period if its plan changes in the future.

Under the U.S. Commercialization and Distribution Agreement (the "U.S. Distribution Agreement") with Nippon Shinyaku the transaction price consists of variable shared revenue payments and fixed components in the form of an upfront payment and milestones. The timing of the fixed component of the transaction price is upfront, however, the performance obligation is satisfied over a period of time, which is the estimated duration of the HOPE-3 clinical trial, Cohort A arm. Therefore, upon receipt of the upfront payment and achievement of milestones, a contract liability is recorded which represents deferred revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the related revenue recognition.

Grant Income

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 grant award (the "CIRM Award") from the California Institute for Regenerative Medicine ("CIRM") 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 5 - "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. No grant income was recognized during the three months ended March 31, 2024 and 2023.

Research and Development

Costs relating to the design and development of new products are expensed as research and development as incurred in accordance with FASB ASC 730-10, *Research and Development*. Research and development costs amounted to approximately $11.1 million and approximately $7.7 million for the three months ended March 31, 2024 and 2023 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 $9.7 million and $7.8 million for the three months ended March 31, 2024 and 2023, 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, 2024 and 2023, the Company's other comprehensive income (loss) was $71,888 and $(10,258), 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, 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 condensed 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 discussions 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 condensed 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.

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, 2024 and 2023, warrants and options to purchase 15,670,163 and 7,971,557 shares of common stock, respectively, have been excluded from the computation of potentially dilutive securities. Potentially dilutive shares of common stock, 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, 2024 and 2023.

Fair Value Measurements

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

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

The following table summarizes the fair value measurements by level at March 31, 2024 and December 31, 2023 for assets and liabilities measured at fair value on a recurring basis:

	March 31, 2024			
	Level I	Level II	Level III	Total
Marketable Securities	$ 33,702,431	$ —	$ —	$ 33,702,431

	December 31, 2023			
	Level I	Level II	Level III	Total
Marketable Securities	$ 24,792,846	$ —	$ —	$ 24,792,846

Carrying amounts reported in the balance sheet of cash and cash equivalents, receivables, 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 October 2023, the FASB issued ASU 2023-06, Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative. This standard was issued in response to the SEC's disclosure update and simplification initiative, which affects a variety of topics within the Accounting Standards Codification. The amendments apply to all reporting entities within the scope of the affected topics unless otherwise indicated. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. The Company is currently evaluating the impact this guidance will have on its financial statement 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. STOCKHOLDER'S EQUITY

ATM Program

The Company established an "at-the-market" program (the "ATM Program") on June 21, 2021, with an aggregate offering price of up to $75.0 million, pursuant to a Common Stock Sales Agreement with Wainwright by which Wainwright has 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.

From June 21, 2021 through March 31, 2024, the Company sold an aggregate of 3,423,375 shares of common stock under the ATM Program at an average price of approximately $5.55 per share for gross proceeds of approximately $19.0 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to Wainwright, as well as legal and accounting fees in the aggregate amount of approximately $0.7 million. Additionally, subsequent to March 31, 2024, the Company sold shares under the ATM Program (see Note 9 – "Subsequent Events").

September 2023 Financing

On September 29, 2023, the Company entered into Securities Purchase Agreements with its commercial partner, Nippon Shinyaku and funds associated with Highbridge Capital Management, LLC (the "Investors"), pursuant to which the Company agreed to issue and sell to the Investors, in a registered direct offering (the "Registered Direct Offering"), an aggregate of 4,935,621 shares of its common stock, par value $0.001 per share, at a price per share of $4.66 for an aggregate purchase price of approximately $23.0 million. Each share of common stock offered was sold with a warrant to purchase one share of common stock at an exercise price of $5.70 per share. Each warrant became exercisable beginning six months after issuance and will expire seven years from the date of issuance. As part of the Registered Direct Offering, the Company agreed not to issue or sell shares (subject to customary exceptions for employee stock option issuances and other customary exceptions) for a period of 30 days following the date of the prospectus supplement that was used in the Registered Direct Offering. That prospectus was dated September 29, 2023, and the Company "lock-up" expired on October 29, 2023. The Company's directors and executive officers also entered into "lock-up" agreements with the placement agent in the Registered Direct Offering, which agreements expired on the 60th day following the date of the Securities Purchase Agreements.

Outstanding Shares

At March 31, 2024, the Company had 31,600,183 shares of common stock issued and outstanding.

3. STOCK AWARDS, WARRANTS AND OPTIONS

Warrants

The following table summarizes all warrant activity for the three months ended March 31, 2024:

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2023	5,041,403	$ 5.61
Granted	—	—
Exercised	—	—
Outstanding at March 31, 2024	5,041,403	$ 5.61

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

Type	Grant Date	Warrants Outstanding March 31, 2024	Warrants Outstanding December 31, 2023	Exercise Price per Share	Expiration Date
Common Warrants	12/19/2019	40,782	40,782	$ 1.10	12/19/2024
Common Warrants	3/27/2020	65,000	65,000	$ 1.5313	3/27/2025
Common Warrants	10/3/2023	4,935,621	4,935,621	$ 5.70	10/3/2030
		5,041,403	5,041,403		

Stock Options

The Company's Board of Directors (the "Board") has approved five 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"), (iv) the 2020 Equity Incentive Plan (the "2020 Plan"), and (v) the 2021 Equity Incentive Plan (the "2021 Plan"). At this time, the Company only issues options under the 2020 Plan and the 2021 Plan and no longer issues options under the 2006 Stock Option Plan, the 2012 Plan, or the 2012 Non-Employee Director Plan.

In June 2021, the Company's stockholders approved the 2021 Plan, which authorized 3,500,000 shares of common stock reserved under the 2021 Plan for the issuance of stock awards. The number of shares available for issuance under the 2021 Plan shall be automatically increased on January 1 of each year, commencing with January 1, 2022, by an amount equal to the lesser of 5% of the outstanding shares of Common Stock as of the last day of the immediately preceding fiscal year or such number of shares determined by the compensation committee of the Board. On January 1, 2024 and 2023, 1,557,416 and 1,262,070 shares were added under the 2021 Plan, respectively.

As of March 31, 2024, 377,866 options remain available for issuance under the respective stock option plans.

The Company's stock option plans are administered by the Board, in conjunction with 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. 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. Stock options are granted with an exercise price not less than 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, 2024 and 2023 were approximately $4.59 and $3.47 per share, respectively.

The Company estimates the fair value of each option award using the Black-Scholes option-pricing model. The company used the following assumptions to estimate the fair value of stock options issued during the three months ended March 31, 2024 and 2023:

	Three months ended March 31, 2024	Three months ended March 31, 2023
Expected volatility	109 - 119 %	115 - 121 %
Expected term	5 - 7 years	5 - 7 years
Dividend yield	0 %	0 %
Risk-free interest rates	3.9 - 4.3 %	3.6 - 3.9 %

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

	Three months ended March 31,	
	2024	2023
General and administrative	$ 2,277,685	$ 1,754,223
Research and development	987,727	440,561
Total	$ 3,265,412	$ 2,194,784

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. The Company accounts for forfeitures upon occurrence.

As of March 31, 2024, the total unrecognized fair value compensation cost related to non-vested stock options was approximately $21.2 million, which is expected to be recognized over a weighted average period of approximately 1.6 years.

The following is a schedule summarizing employee and non-employee stock option activity for the three months ended March 31, 2024:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2023	8,227,404	$ 3.46	
Granted	2,541,226	5.28	
Exercised	(10,512)	3.63	$ 30,421
Expired/Cancelled	(129,358)	5.68	
Outstanding at March 31, 2024	10,628,760	$ 3.87	$ 31,029,555
Exercisable at March 31, 2024	5,000,341	$ 3.07	$ 18,581,909

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.

4. CONCENTRATIONS

Concentration of Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash, cash equivalents, and marketable securities. The Company maintains accounts at three financial institutions. These accounts are insured by the Federal Deposit Insurance Corporation (the "FDIC") for up to $250,000 and/or the Securities Investor Protection Corporation, as applicable. The Company's cash, cash equivalents, and marketable securities in excess of the FDIC insured limits as of March 31, 2024, were approximately $39.7 million. The Company monitors the financial stability of the financial institutions with which it maintains accounts and believes it is not exposed to any significant credit risk in cash and cash equivalents. Historically, the Company has not experienced any significant losses in such accounts and does not believe it is exposed to any significant credit risk due to the quality nature of the financial instruments in which the money is held.

5. 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 1/2 HOPE-Duchenne clinical trial investigating CAP-1002 for the treatment of DMD-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 the CIRM Loan Policy and CIRM Grants Administration Policy for Clinical Stage Projects (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. Depending on the timing of our election, additional funds may be owed. If we elect to do so, Capricor would be required to repay the amounts awarded by CIRM; therefore, the Company accounts for this award as a liability rather than income.

In 2019, Capricor completed all milestones and close-out activities associated with the CIRM Award and expended all funds received. As of March 31, 2024, Capricor's liability balance for the CIRM Award was approximately $3.4 million.

6. COMMITMENTS AND CONTINGENCIES

Short-Term Operating Leases

Capricor leases office space in Beverly Hills, California from The Bubble Real Estate Company, LLC ("Bubble Real Estate") pursuant to a lease beginning in 2013. Capricor subsequently entered into several amendments modifying certain terms of the lease. Effective January 1, 2021, we entered into a month-to-month lease amendment with Bubble Real Estate, which is terminable by either party upon 90 days' written notice to the other party. Commencing in July 2022, the monthly lease payment was $7,869 per month. Effective July 1, 2023, the monthly lease payment was reduced to $7,619 per month.

Commencing March 13, 2024, we entered into a License and Services Agreement with Azzur Cleanrooms-on-Demand – San Diego, LLC (the "Azzur License Agreement") pursuant to which we have been granted an exclusive license to use certain space and the non-exclusive right to use certain equipment and property for our early phase clinical and/or

pre-clinical manufacturing purposes. Our estimated license fee is approximately $110,615 per month for a term of approximately 6.5 months.

Expenses incurred under short-term operating leases for the three months ended March 31, 2024 and 2023 were $92,913 and $23,607, respectively. Short-term operating lease payments for the three months ended March 31, 2024 and 2023 were $384,357 and $23,607, respectively. As of March 31, 2024, the Company recorded $291,444 as a prepaid expense related to an upfront payment made pursuant to the Azzur License Agreement on the Company's condensed consolidated balance sheet.

Long-Term Operating Leases

Capricor leases facilities in Los Angeles, California from Cedars-Sinai Medical Center ("CSMC"), pursuant to a lease (the "Facilities Lease") entered into in 2014. Capricor has subsequently entered into several amendments modifying certain terms of the lease. In July 2022, we entered into an amendment for an additional 24-month period extending the term through July 31, 2024 with a monthly lease payment of $10,707. We entered into another amendment effective August 1, 2024 pursuant to which Capricor was granted an option to extend the lease for an additional 24-month period extending the term through July 31, 2026 with a monthly lease payment of $11,028.

Capricor leases facilities in San Diego, California from Altman Investment Co., LLC ("Altman"). The Company entered into a lease agreement commencing October 1, 2021 with Altman for 9,396 square feet of office and laboratory space (the "San Diego Lease"). The rent is subject to a 3.0% annual rent increase during the initial lease term of five years, plus certain operating expenses and taxes. The San Diego Lease contains an option for Capricor to renew it for an additional term of five years. The Company has subsequently entered into several amendments to the San Diego Lease increasing the square footage of the premises. Effective December 1, 2022, the monthly lease payment was $51,444 per month. Effective October 1, 2023, the monthly lease payment was increased to $58,409 per month.

Effective November 1, 2021, the Company entered into a vivarium agreement with Explora BioLabs, Inc. ("Explora"), a Charles River Company, for vivarium space and services. Under the terms of the agreement, the Company is obligated to pay a base rent of $4,021 per month for an exclusive large vivarium room located in San Diego, California. In December 2022, we were notified by Explora of a monthly rent escalation of 4.5% bringing the base rent to approximately $4,202 per month effective January 1, 2023. Additionally, effective January 1, 2024, we entered into an amendment for an additional 24-month period extending the term through December 31, 2025 with a monthly lease payment of $4,370 commencing on January 1, 2024 with a 4.0% annual rent increase.

The long-term real estate operating leases are included in "lease right-of-use assets, net" on the Company's condensed consolidated balance sheet and represent the Company's right-to-use the underlying assets for the lease term. The Company's obligation to make lease payments are included in "lease liabilities, current" and "lease liabilities, net of current" on the Company's condensed consolidated balance sheet.

The tables below exclude short-term operating leases. The following table summarizes maturities of lease liabilities and the reconciliation of lease liabilities as of March 31, 2024:

2024	$ 668,233
2025	914,220
2026	634,889
2027	—
2028	—
Total minimum lease payments	2,217,342
Less: imputed interest	(196,343)
Total operating lease liabilities	$ 2,020,999
Included in the consolidated balance sheet:	
Current portion of lease liabilities	$ 771,506
Lease liabilities, net of current	1,249,493
Total operating lease liabilities	$ 2,020,999
Other Information:	
Weighted average remaining lease term	2.44 years
Weighted average discount rate	7.40%

As of March 31, 2024, ROU assets for operating leases were approximately $1.8 million and operating lease liabilities were approximately $2.0 million. The following table contains a summary of the lease costs recognized and lease payments pertaining to the Company's long-term operating leases under ASC 842 for the period indicated.

	Three months ended March 31,	
	2024	2023
Lease costs	$ 210,357	$ 192,606
Lease payments	226,625	199,058

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. The Company records a loss contingency reserve for a legal proceeding when it considers the potential loss probable and it can reasonably estimate the amount of the loss or determine a probable range of loss. The Company has not recorded any material accruals for loss contingencies as of March 31, 2024. The Company has received a letter from CSMC alleging certain overdue payment obligations and alleged breaches (see Note 7 – "License and Distribution Agreements").

Accounts Payable

During the normal course of business, disputes with vendors may arise. If a vendor disputed 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 7 – "License and Distribution Agreements").

Additionally, the Company is a party to various agreements with contract research, manufacturing and other organizations 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 approves 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 under these severance packages has been recorded as of March 31, 2024.

7. LICENSE AND DISTRIBUTION AGREEMENTS

Intellectual Property Rights for 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 JHU. 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.

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. Various amendments were entered into to revise certain provisions of the JHU License Agreement. 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 maximum aggregate amount of milestone payments payable under the JHU License Agreement, as amended, is $1,850,000. In 2022, Capricor paid the $250,000 development milestone related to the Phase 2 study pursuant to the terms of the JHU License Agreement. The next milestone is triggered upon successful completion of a full Phase 3 study for which a payment of $500,000 will be 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 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 provided for the grant of an exclusive, world-wide, royalty-bearing license of JHU's co-owned rights 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. The JHU Exosome License Agreement was terminated by Capricor on December 15, 2023.

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 cardiosphere-derived cell ("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, subject to certain exclusions. 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 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.

Capricor and CSMC have entered into several 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 and extend the timing of certain development milestones, among other things. Capricor reimbursed CSMC for certain attorneys' fees and filing fees incurred in connection with the additional patent applications.

In March 2024, we received a letter from CSMC alleging that pursuant to the Amended CSMC License Agreement between CSMC and Capricor, Capricor has certain overdue payment obligations to CSMC arising out of a milestone payment received by Capricor pursuant to the U.S. Distribution Agreement entered into between Capricor and Nippon Shinyaku. Capricor has received a milestone payment of $10.0 million under its U.S. Distribution Agreement with Nippon Shinyaku, and CSMC is claiming 10.0% of this milestone payment, or $1.0 million, is owed to them. The notice letter requests that Capricor cure the alleged breaches of the Amended CSMC License Agreement, and reserves CMSC's purported right to terminate the Amended CSMC License Agreement if such alleged breaches are not cured. We dispute the allegations in the letter from CSMC and intend to vigorously defend our position and pursue all available remedies, but there is no guarantee that any disputes that we have with CSMC will be resolved or if resolved, will not result in our incurring certain payment and other obligations.

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 CDC-derived 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.

Capricor and CSMC have entered into several 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, 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, and converted certain exclusive rights to co-exclusive rights. 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.

Cell Line License Agreement with Life Technologies

On March 7, 2022, Capricor entered into a non-exclusive cell line license agreement with Life Technologies Corporation, a subsidiary of Thermo Fisher Scientific, Inc., for the supply of certain cells which we will use in connection with the development of our exosomes platform. An initial license fee payment was made in 2022 and additional milestone fees may become due based on the progress of our development program.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: United States)

On January 24, 2022, Capricor entered into the U.S. Distribution Agreement with Nippon Shinyaku, a Japanese corporation. Under the terms of the U.S. Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in the United States of CAP-1002, for the treatment of DMD.

Under the terms of the U.S. Distribution Agreement, Capricor will be responsible for the conduct of the HOPE-3 trial as well as the manufacturing of CAP-1002. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in the United States. Pursuant to the U.S. Distribution Agreement, Capricor received an upfront payment of $30.0 million in the first quarter of 2022. The first milestone payment of $10.0 million was paid upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. Additionally, there are potential milestones totaling up to $90.0 million leading up to and including the BLA approval. Further, there are various potential sales-based milestones, if commercialized, tied to the achievement of certain sales thresholds for annual net sales of CAP-1002 of up to $605.0 million. Further, pursuant to the US Distribution Agreement, Capricor has the obligation to sell commercial product to Nippon Shinyaku, subject to regulatory approval, and Capricor will have the right to receive a meaningful mid-range double-digit share of product revenue.

The Company has evaluated the U.S. Distribution Agreement in accordance with ASU 606, *Revenue for Contracts from Customers*. At the inception, the Company identified one distinct performance obligation. The Company determined that the performance obligation is the conduct of the HOPE-3, Phase 3 clinical study.

The Company determined the transaction price totaled $40.0 million, which was the upfront payment of $30.0 million and $10.0 million milestone payment. The Company has excluded any future milestone or shared revenue payments from this transaction price to date based on probability. The Company has allocated the $40.0 million transaction price to its one distinct performance obligation. Revenue will be recognized using a proportional performance method in relation to the completion of the HOPE-3 clinical study, Cohort A arm, to determine the extent of progress towards completion. Under this method, the transaction price is recognized over the contract's entire performance period using a cost percentage per patient visit relative to the total estimated cost of patient visits.

For the three months ended March 31, 2024, the Company recognized approximately $4.9 million as revenue compared to approximately $3.0 million for the three months ended March 31, 2023. In relation to the U.S. Distribution Agreement, as of March 31, 2024, the Company recorded approximately $7.4 million as current deferred revenue on the Company's consolidated balance sheets.

The Company had no opening or closing contract asset balances recognized. The difference between the opening and closing balances of the Company's contract liability results from the Company performance of services in connection to its performance obligation.

The transaction price allocated to remaining performance obligations represents contracted revenue that has not yet been recognized. As of March 31, 2024, remaining performance obligations related to the U.S. Distribution Agreement were approximately $7.4 million. At this time, we estimate 100% of the remaining performance obligations are expected to be recognized over the next 12 months. Remaining performance obligations estimates are subject to change.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: Japan)

On February 10, 2023, Capricor entered into a Commercialization and Distribution Agreement (the "Japan Distribution Agreement") with Nippon Shinyaku. Under the terms of the Japan Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in Japan of CAP-1002 for the treatment of DMD.

Under the terms of the Japan Distribution Agreement, Capricor received an upfront payment of $12.0 million in the first quarter of 2023, and in addition, Capricor may potentially receive additional development and sales-based milestone payments of up to approximately $89.0 million, subject to foreign currency exchange rates, and a meaningful double-digit share of product revenue. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in Japan. Capricor will be responsible for the conduct of clinical development in Japan, as may be required, as well as the manufacturing of CAP-1002. Subject to regulatory approval, Capricor will sell commercial product to Nippon Shinyaku in Japan. In addition, Capricor or its designee will hold the Marketing Authorization in Japan if the product is approved in that territory.

The Company has evaluated the Japan Distribution Agreement in accordance with ASU 606, *Revenue for Contracts from Customers*. The Company determined the initial transaction price totaled $12.0 million, which was the upfront payment fee. The Company has excluded any future milestone or shared revenue payments from this transaction price to date based on probability. At this time, the Company is evaluating the regulatory pathway to achieve potential product approval in this territory. Until such time, the Company cannot identify any distinct performance obligation. As such, the Company has recorded the entire upfront payment fee of $12.0 million as current deferred revenue on the Company's condensed consolidated balance sheets as of March 31, 2024.

8. RELATED PARTY TRANSACTIONS

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. As of March 31, 2024 and December 31, 2023, $10,000 was recorded in accounts payable and accrued expenses related to this Consulting Agreement.

In January 2024, Capricor entered into a Consulting Agreement with Michael Kelliher, a member of its Board of Directors, related to business development services unrelated to his duties on behalf of the Board, whereby he was granted an option to purchase 30,000 shares of the Company's common stock.

9. SUBSEQUENT EVENTS

Additional Sales under ATM Program

Subsequent to March 31, 2024 and through May 13, 2024, the Company sold an aggregate of 165,131 shares of common stock under the ATM Program at an average price of approximate $6.89 per share for gross proceeds of approximately $1.1 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to the placement agent in the aggregate amount of approximately $36,400.

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.

Company Overview

Capricor Therapeutics, Inc. is a clinical-stage biotechnology company focused on the development of transformative cell and exosome-based therapeutics for treating Duchenne muscular dystrophy ("DMD"), a rare form of muscular dystrophy which results in muscle degeneration and premature death, and other diseases with high unmet medical needs.

Since our inception, we have devoted substantial resources to developing CAP-1002 and our other product candidates including our exosomes platform, developing our manufacturing processes, staffing our company and providing general and administrative support for these operations. We do not have any products approved for sale. Our ability to eventually generate any product revenue sufficient to achieve profitability will depend on the successful development, approval and eventual commercialization of CAP-1002 for the treatment of DMD and our other product candidates. If successfully developed and approved, we intend to commercialize CAP-1002 in the United States and Japan with our partner, Nippon Shinyaku Co., Ltd., a Japanese corporation ("Nippon Shinyaku"), and may enter into licensing agreements or strategic collaborations in other markets. If we generate product sales or enter into licensing agreements or strategic collaborations, or further distribution relationships, we expect that any revenue we generate will fluctuate from quarter-to-quarter and year-to-year as a result of the timing and amount of any product sales, license fees, milestone payments and other payments. If we fail to complete the development of our product candidates in a timely manner, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

A summary description of our key product candidates, is as follows:

- **CAP-1002 for the treatment of DMD (Phase 3):** Our core program is focused on the development and commercialization of a cell therapy technology (referred herein as CAP-1002) comprised of CDCs, which are a population of stromal cells isolated from donated cells of healthy human hearts, for the treatment of DMD. CAP-1002 is designed to slow disease progression in DMD through the immunomodulatory, anti-inflammatory, and anti-fibrotic actions of CDCs, which are mediated by secreted exosomes laden with bioactive cargo. Among the cargo elements known to be bioactive in CDC exosomes are microRNAs. Collectively, these non-coding RNA species alter gene expression in macrophages and other target cells, dialing down generalized inflammation and stimulating tissue regeneration in DMD (and in a variety of other inflammatory diseases). This mechanism of action, consistent with the changes observed in clinical studies to date in circulating inflammatory biomarkers, contrasts with that of exon-skipping oligonucleotides and gene therapy approaches, which aim to restore dystrophin expression. DMD is a rare form of muscular dystrophy which results in muscle degeneration and premature death. DMD pathophysiology is driven by the impaired production of functional dystrophin which normally functions as a structural protein in muscle. The reduction of functional dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. 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. Our CAP-1002 cell therapy program for the treatment of DMD is currently in Phase 3 clinical development in the United States, for which we expect to have top-line data available in the fourth quarter of 2024.

To date, we have completed two promising clinical trials investigating CAP-1002 for DMD. Data from the first trial, a Phase I/II trial named HOPE-Duchenne, suggested improvements in skeletal and cardiac endpoints. In HOPE-2, a Phase II clinical trial conducted in the United States, CAP-1002 was used to treat patients with late-stage DMD. In March 2022, we announced that the final one-year results from HOPE-2 were published in The Lancet showing that the trial met its primary efficacy endpoint of the mid-level dimension of the Performance of the Upper Limb ("PUL") v1.2 (p=0.01) and additional positive endpoints of full PUL v2.0 (p=0.04) and a cardiac endpoint of left ventricular ejection fraction (p=0.002). CAP-1002 was generally safe and well-tolerated throughout the studies.

Additionally, we are currently conducting an open label extension ("OLE") study of the HOPE-2 trial in which 12 patients have elected to continue treatment of CAP-1002. We announced positive one-year and two-year results from this ongoing OLE study. The HOPE-2-OLE study previously met its primary endpoint at the one-year timepoint on the PUL v2.0 scale (p=0.02). At the two-year timepoint, data showed statistically significant differences in the PUL v2.0 in the OLE treatment group when compared to the original rate of decline of the placebo group from HOPE-2 after one-year (p=0.021). CAP-1002 treatment during the OLE portion of the study continues to yield a consistent safety profile and has been well-tolerated throughout the study. At this time, we expect to have three-year data available from this OLE study in the second quarter of 2024.

Phase 3 (HOPE-3) Clinical Trial: HOPE-3 is a Phase 3, multi-center, randomized, double-blind, placebo-controlled clinical trial comprised of two cohorts evaluating the safety and efficacy of CAP-1002 in participants with DMD and impaired skeletal muscle function who are on a stable regimen of systemic glucocorticoids. Non-ambulatory and ambulatory boys who meet eligibility criteria are randomly assigned to receive either CAP-1002 or placebo every 3 months for 4 doses during the first 12-months of the study. Approximately 102 eligible study subjects will participate in this dual-cohort study. A primary safety and efficacy analysis will be performed for each individual cohort (referred to as Cohort A or Cohort B) at month 12, following 4 administrations of CAP-1002 or placebo. In November 2023, we announced completion of enrollment for Cohort A where 61 subjects were randomized to either CAP-1002 or placebo in a 1:1 ratio. In December 2023, we announced a positive outcome of the interim futility analysis for Cohort A of HOPE-3, which was reviewed by the Data Safety Monitoring Board ("DSMB"). This resulted in a favorable recommendation to continue the HOPE-3 trial as planned. At this time, we expect to have topline data available from Cohort A in the fourth quarter of 2024 and this dataset is intended to support a Biologics License Application ("BLA") submission. Cohort A uses product manufactured at our Los Angeles facility.

The primary outcome measure of the HOPE-3 study will be the Performance of the Upper Limb ("PUL") v2.0, a validated tool specifically designed for assessing high (shoulder), mid (elbow) and distal (wrist and hand) functions, with a conceptual framework reflecting weakness progression in upper limb function. HOPE-3 will also measure various secondary endpoints including cardiac function assessments.

We have also been enrolling Cohort B which is currently designed to enroll approximately 44 subjects randomized to either CAP-1002 or placebo in a 1:1 ratio. At this time, we are evaluating multiple options for the next steps in connection with Cohort B as the FDA is no longer requiring it for potential product approval. Cohort B uses product manufactured at our San Diego facility.

Under our RMAT designation, in March 2024, we had a Type-B CMC meeting with FDA where we discussed the progress of our CMC development program for CAP-1002 to support a BLA submission. At that meeting the FDA agreed that comparability between drug product manufactured at our two different facilities (Los Angeles and San Diego) has been demonstrated using the provided analytical comparability data. This will now allow for the use of CAP-1002 drug product manufactured at our San Diego manufacturing facility upon potential product approval and approval of the San Diego facility. Furthermore, the FDA advised us to include discussion for a pre-BLA meeting and rolling BLA schedule in our upcoming Type-B meeting which is scheduled to be held in the second quarter of 2024 to discuss these topics.

The regulatory pathway for CAP-1002 is supported by RMAT designation as well as orphan drug designation. In addition, if Capricor were to receive FDA marketing approval for CAP-1002 for the treatment

of DMD, Capricor would be eligible to receive a Priority Review Voucher ("PRV") based on its previous receipt of a rare pediatric disease designation. Capricor retains full rights to the PRV, if received. Further, Capricor has entered into two Commercialization and Distribution Agreements with Nippon Shinyaku appointing Nippon Shinyaku as its exclusive distributor of CAP-1002 in the United States and Japan.

- **Exosome-Based Platform (Preclinical):** 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 the delivery of their cargo into the cytosol of target cells. Exosomes act as messengers to regulate the functions of neighboring or distant cells and have been shown to regulate functions such as cell survival, proliferation, inflammation and tissue regeneration. Their size, low or null immunogenicity and ability to communicate in native cellular language potentially make them an exciting new class of therapeutic agents with the potential to expand our ability to address complex biological responses. Because exosomes are cell-free substances, they can be stored, handled, reconstituted and administered in similar fashion to common biopharmaceutical products such as antibodies.

  We are focused on developing a precision-engineered exosome platform technology that has the ability to deliver defined sets of effector molecules that exert their effects through defined mechanisms of action. Aspects of our exosome pipeline have been supported through collaborations and alliances. Our collaborations and research around exosomes include the National Institutes of Health ("NIH"), the National Institute of Allergy and Infectious Diseases ("NIAID"), Johns Hopkins University ("JHU"), the Department of Defense ("DoD"), the U.S. Army Institute of Surgical Research ("USAISR"), and Cedars-Sinai Medical Center ("CSMC"). We have published preclinical data on our StealthX™ platform showing the rapid development of a recombinant protein-based vaccine for immunization and prevention against SARS-CoV-2, the virus causing COVID-19. Our platform builds on advances in fundamental RNA and protein science, targeting technology and manufacturing, providing us the opportunity to potentially build a broad pipeline of new therapeutic candidates. Recently, we were selected to be part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines providing broader and more durable protection for COVID-19. As part of Project NextGen, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, will conduct a Phase 1 clinical study with our StealthX™ vaccine, subject to regulatory approval. At this time, we have submitted an Investigational New Drug Application ("IND") to the FDA for our StealthX™ vaccine, which is currently under review and we anticipate that once the IND is approved, that NIAID plans to initiate this trial in late 2024. Furthermore, If NIAID finds that our StealthX™ vaccine meets its criteria for safety and efficacy, they may consider our program for a funded Phase 2. At this time, we are developing exosome-based vaccines and therapeutics for infectious diseases, monogenic diseases and other potential indications. Our current strategy is focused on securing partners who will provide capital and additional resources to enable us to bring this program into the clinic.

As of March 31, 2024, we had cash, cash equivalents, and marketable securities totaling approximately $39.9 million. In the fourth quarter of 2023, we announced a positive outcome of the interim futility analysis for HOPE-3, which was reviewed by the Data Safety Monitoring Board. This resulted in a favorable recommendation to continue the HOPE-3 trial as planned, and in accordance with our U.S. Distribution Agreement with Nippon Shinyaku, triggered a milestone payment of $10.0 million which was received in January 2024. We estimate our current cash balance will fund our operating expenses and capital expenditure requirements into the first quarter of 2025. This expectation excludes any additional potential milestone payments under our Commercialization and Distribution agreements with Nippon Shinyaku. We have not generated any revenues from the commercial sale of products. We will not be able to generate any product revenues until, and only if, we receive approval to sell our drug candidates from the FDA or other regulatory authorities.

Due to our significant research and development expenditures, and general administrative costs associated with our operations, we have generated substantial operating losses in each period since our inception. Our net losses were approximately $9.8 million and approximately $7.8 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of approximately $169.2 million. We expect to incur significant expenses and operating losses for the foreseeable future.

During the three months ended March 31, 2024, we sold 447,221 shares of common stock at an average price of approximately $5.33 per share pursuant to a sales agreement by and between us and H.C. Wainwright & Co. LLC ("Wainwright") under our at-the-market offering, resulting in net proceeds of approximately $2.3 million.

Recent Operational Developments

CAP-1002 DMD Program Updates

- Enrollment has been completed for Cohort A in our HOPE-3, Phase 3 clinical trial which enrolled 61 subjects randomized to either CAP-1002 or placebo in a 1:1 ratio.
  - Next steps for Cohort A: plan to readout top-line data in the fourth quarter of 2024.
- Announced a positive outcome from a Type-B CMC FDA meeting held in the first quarter of 2024. In the meeting, the FDA affirmed alignment on the following topics:
  - Comparability between drug product manufactured at our two different facilities (Los Angeles and San Diego) has been demonstrated using the provided analytical comparability data.
  - This will now allow for the use of CAP-1002 drug product manufactured at our San Diego manufacturing facility upon potential product approval (subject to approval of the facility).
- Announced we were granted a Type-B clinical FDA meeting scheduled to be held in May 2024 to continue discussing our pathway to BLA.
  - The FDA advised us to include discussion and a request for a pre-BLA meeting and rolling BLA schedule at this meeting.
  - We also plan to share with FDA our HOPE-2 OLE 3-year safety and efficacy data.
- Announced further specifics under our U.S. Distribution and Commercialization Agreement with Nippon Shinyaku.
  - Capricor will receive a meaningful mid-range double-digit share of product revenue. For clarity, mid-range falls in between 30-50%, which sum will be offset by the amounts paid to us as the transfer price for the purchase of the product.
- Announced we are on track to enroll 44 U.S. based patients by the end of the second quarter 2024 in Cohort B HOPE-3 clinical trial.
  - Next steps for Cohort B: We are evaluating various options, with one of such options being the opportunity for an expansion of Cohort B to include European patients.
- Announced the scale-up of manufacturing capacity of CAP-1002 in our new San Diego facility, intended for commercial use, subject to regulatory approval.
  - Currently, this facility is fully operational, staffed and producing doses for clinical use. Along with BLA readiness activities, we are also actively preparing for commercial runs.
- Presented at the Parent Project Muscular Dystrophy (PPMD) Cardiac Workshop III. Capricor was featured in a panel on industry perspectives on cardiac monitoring in DMD clinical trials.
- Presented at the 2024 Muscular Dystrophy Association (MDA) Clinical & Scientific Conference sharing the previously presented positive 24-month results from our HOPE-2 OLE study.

Exosome Program Updates

- Announced that our proprietary StealthX™ exosome-based multivalent vaccine (StealthX™ vaccine) for the prevention of SARS-CoV-2 was selected to be part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines.
  - As part of Project NextGen, NIAID, part of the National Institutes of Health, will conduct and fund a Phase 1 clinical trial with our StealthX™ vaccine.
  - Under the terms of the collaboration, Capricor will supply the investigational product and NIAID's Division of Microbiology and Infectious Diseases (DMID) will conduct the trial.
  - If NIAID finds that our StealthX™ vaccine meets its criteria for safety and efficacy, they may consider our program for a funded Phase 2.

- Currently, in collaboration with an undisclosed pharmaceutical company, we are also investigating the therapeutic application of our StealthX™ exosome platform.
- Presented data in an oral presentation at the American Society of Gene and Cell Therapy (ASGCT) 27th Annual Meeting. The findings highlight a potential exosome-based approach for the treatment of arginase-1 deficiency (ARG1-D), a rare genetic metabolic disease characterized by complete or partial lack of the enzyme arginase in the liver and red blood cells. The data from this preclinical study further characterize our StealthX™ exosome platform.
- Presented data at the International Society of Extracellular Vesicles (ISEV) Annual Meeting 2024. Highlights from the abstract included data showing targeted cargo delivery to mouse lower limbs by exosomes carrying a muscle targeting moiety by intravenous injection.

Corporate Updates

- Announced receipt of our first milestone payment of $10.0 million received in the first quarter of 2024 under our U.S. Distribution and Commercialization Agreement with Nippon Shinyaku. This milestone was triggered upon the positive outcome from the interim futility analysis for Cohort A of the HOPE-3 clinical trial.
- Presented at H.C. Wainwright 2nd Annual Cell Therapy Conference.
- Presented at the Cantor Fitzgerald's Muscular Dystrophy Symposium.

As we seek to develop and commercialize CAP-1002 or any other product candidates including those related to our exosomes program, we anticipate that our expenses will increase significantly and that we will need substantial additional funding to support our continuing operations. Until such time when we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity financings, debt financings or other sources, which may include licensing agreements or strategic collaborations or other distribution agreements. We may be unable to raise additional funds or enter into such agreements or arrangements when needed on favorable terms, if at all. If we fail to raise capital or other potential funding or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development or commercialization of CAP-1002 or our other product candidates.

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 product candidates. Developing biological 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 public equity sales of securities and upfront payments pursuant to our U.S. and Japan Distribution Agreements with Nippon Shinyaku. 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 in the US and in other territories across the world.

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 conditions. Stock-based compensation expense is included in the condensed consolidated statements of operations under general and administrative ("G&A") or research and

development ("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

Clinical Development Income. Clinical development income for the three months ended March 31, 2024 and 2023 was approximately $4.9 million and $3.0 million, respectively. The Company began to recognize the $30.0 million upfront payment received from Nippon Shinyaku related to an Exclusive Commercialization and Distribution Agreement (the "U.S. Distribution Agreement") with Nippon Shinyaku in the third quarter of 2022. The Company began to recognize the $10.0 million milestone payment in connection with the U.S. Distribution Agreement in the fourth quarter of 2023. Revenue is ratably recognized using a proportional performance method in relation to the completion of the HOPE-3 clinical trial (Cohort A).

Operating Expenses

Research and Development Expenses. R&D expenses consist primarily of compensation and other 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, certain legal expenses resulting from intellectual property prosecution, stock-based compensation expense and other expenses relating to the design, development, testing and enhancement of our product candidates.

The following table summarizes our R&D expenses by category for each of the periods indicated:

	Three months ended March 31,			
	2024	2023	Change ($)	Change (%)
Compensation and other personnel expenses	$ 3,416,590	$ 2,250,753	$ 1,165,837	52 %
Duchenne muscular dystrophy (CAP-1002)	5,278,644	3,838,811	1,439,833	38 %
Exosomes platform research	663,838	581,986	81,852	14 %
Facility expenses	484,550	305,866	178,684	58 %
Stock-based compensation	987,727	440,560	547,167	124 %
Depreciation	179,167	137,750	41,417	30 %
Research and other	90,497	105,793	(15,296)	(14)%
Total research and development expenses	$ 11,101,013	$ 7,661,519	$ 3,439,494	45 %

R&D expenses for the three months ended March 31, 2024 increased by approximately $3.4 million, or 45%, compared with the three months ended March 31, 2023. The increase was primarily driven by the following:

- $1.2 million increase in compensation and other personnel expenses primarily due to increases in headcount;
- $1.4 million increase in DMD (CAP-1002) program primarily due to the enrollment of our HOPE-3 clinical program, our HOPE-2 OLE clinical trial and our expanded manufacturing production efforts for CAP-1002;
- $0.1 million increase in exosomes platform research primarily due to expansion of exosome manufacturing efforts;
- $0.2 million increase in facility expenses primarily related to increased lease expenses due to our expansion efforts; and
- $0.5 million increase in stock-based compensation expense primarily due to increases in headcount, risk-free rate and stock price, which resulted in an increase in fair value of options issued.

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

The following table summarizes our G&A expenses by category for each of the periods indicated:

	Three months ended March 31,			
	2024	2023	Change ($)	Change (%)
Stock-based compensation	$ 2,277,685	$ 1,754,223	$ 523,462	30 %
Compensation and other personnel expenses	777,933	873,385	(95,452)	(11)%
Professional services	423,994	390,127	33,867	9 %
Facility expenses	76,378	69,746	6,632	10 %
Depreciation	152,239	92,351	59,888	65 %
Other corporate expenses	363,537	330,053	33,484	10 %
Total general and administrative expenses	$ 4,071,766	$ 3,509,885	$ 561,881	16 %

G&A expenses for the three months ended March 31, 2024 increased by approximately $0.6 million, or 16%, compared to the three months ended March 31, 2023. The increase was primarily driven by the following:

- $0.5 million increase in stock-based compensation expense primarily due to an increase in our risk-free rate and stock price, which resulted in an increase in fair value of options issued; and
- $0.1 million increase in depreciation primarily related to leasehold improvements to our San Diego corporate headquarters.

This increase was partially offset by a $0.1 million decrease in compensation and other personnel expenses primarily due to a decrease in recruiting expenses.

Other Income

Investment Income. Investment income for the three months ended March 31, 2024 and 2023 was approximately $0.5 million and approximately $0.4 million, respectively. The increase in investment income for the three months ended March 31, 2024 as compared to the three months ended March 31, 2023 is due to increased interest rates and the higher principal balance in our marketable securities, savings and money market fund accounts.

Products Under Active Development

CAP-1002 for the treatment of DMD – We are currently conducting our HOPE-3, Phase 3 study for DMD and our ongoing OLE study of the HOPE-2 trial for which we expect to spend approximately $25.0 million to $35.0 million in 2024. The expenses for our DMD program will include costs for personnel, clinical, regulatory and manufacturing-related expenses, including expenses related to the scale-up for potential commercial scale manufacturing if our CAP-1002 product is approved.

Exosome-Based Therapeutics and Vaccines – Our exosome platform is in early-stage preclinical development. We expect to spend approximately $3.0 million to $5.0 million during 2024 on development expenses related to our exosomes program, which includes personnel, preclinical studies and manufacturing related expenses for these technologies. Our expenses for this program are primarily focused on the expansion of our engineered exosomes platform including the manufacturing of our StealthX™ vaccine to be used in connection with our collaboration with NIAID.

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 availability of necessary materials required to make our product candidates;
- the costs, requirements and timing of, and the ability to secure, regulatory approvals; and
- the availability and cost of facilities needed to manufacture our products.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of March 31, 2024 and December 31, 2023 and our net increase (decrease) in cash and cash equivalents for the three months ended March 31, 2024 and 2023 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, 2024	December 31, 2023
Cash and cash equivalents	$ 6,215	$ 14,695
Marketable securities	$ 33,702	$ 24,793
Working capital	$ 15,028	$ 19,586
Stockholders' equity	$ 18,435	$ 22,601

	Three months ended March 31,	
Cash flow data	2024	2023
Cash provided by (used in):		
Operating activities	$ (1,268)	$ 4,210
Investing activities	(9,502)	(3,212)
Financing activities	2,290	4
Net increase (decrease) in cash and cash equivalents	$ (8,480)	$ 1,002

Our total cash, cash equivalents and marketable securities as of March 31, 2024 were approximately $39.9 million compared to approximately $39.5 million as of December 31, 2023. The increase in cash, cash equivalents and marketable securities from December 31, 2023 to March 31, 2024 is primarily due to the receipt of the milestone payment of $10.0 from Nippon Shinyaku in the first quarter of 2024 offset by our net loss of approximately $9.8 million for the three months ended March 31, 2024. As of March 31, 2024, we had approximately $31.0 million in total liabilities, of which $19.4 million relates to deferred revenue, and approximately $15.0 million in net working capital.

Cash used in operating activities was approximately $1.3 million for the three months ended March 31, 2024 and cash provided by operating activities was approximately $4.2 million for the three months ended March 31, 2023. The net change of approximately $5.5 million in cash from operating activities is due to the receipt of the milestone payment of $10.0 million from Nippon Shinyaku and deferred revenue. Furthermore, there was an increase of approximately $1.1 million in stock-based compensation and a net decrease of approximately $0.5 million in accounts payable and accrued expenses for the three months ended March 31, 2024 as compared to the same period in 2023. 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 platform 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.

We had cash flow used in investing activities of approximately $9.5 million and approximately $3.2 million for the three months ended March 31, 2024 and 2023, respectively. The change in investing activities for the three months ended March 31, 2024 as compared to the same period of 2023 is due to the net effect from purchases, sales and maturities of marketable securities and the increase of approximately $0.3 million in purchases of property and equipment.

We had cash flow provided by financing activities of approximately $2.3 million and $3,895 for the three months ended March 31, 2024 and 2023, respectively. The increase in cash provided by financing activities for the three months

ended March 31, 2024 as compared to the three months ended March 31, 2023 is due to the net proceeds from the sale of common stock.

From inception through March 31, 2024, we financed our operations primarily through private and public sales of our equity securities, government grants and payments from distribution agreements and collaboration partners. 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 or other distribution agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, complete our clinical trials or if such funds become available to us, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us.

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

- the progress of our clinical and research activities;
- the number and scope of our clinical and 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;
- our ability to successfully manufacture product for our clinical trials and potential commercial use;
- the availability of materials necessary to manufacture our product candidates;
- the costs of manufacturing our product candidates, and the progress of efforts with parties with whom we may enter into commercial manufacturing agreements, if necessary;
- 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.

Collaborations

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: United States)

On January 24, 2022, Capricor entered into a Commercialization and Distribution Agreement (the "U.S. Distribution Agreement") with Nippon Shinyaku, a Japanese corporation. Under the terms of the U.S. Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in the United States of CAP-1002 for the treatment of DMD.

Under the terms of the U.S. Distribution Agreement, Capricor will be responsible for the conduct of the HOPE-3 trial as well as the manufacturing of CAP-1002. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in the United States. Pursuant to the U.S Distribution Agreement, Capricor received an upfront payment of $30.0 million in the first quarter of 2022. The first milestone payment of $10.0 million was paid upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. Capricor received this milestone payment from Nippon Shinyaku in January 2024. Additionally, there are potential milestones totaling up to $90.0 million leading up to and including the BLA approval. Further, there are various potential sales-based milestones, if

commercialized, tied to the achievement of certain sales thresholds for annual net sales of CAP-1002 of up to $605.0 million. Further, pursuant to the U.S. Distribution Agreement, Capricor has the obligation to sell commercial product to Nippon Shinyaku, subject to regulatory approval, and Capricor will have the right to receive a meaningful mid-range double-digit share of product revenue.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: Japan)

On February 10, 2023, Capricor entered into a Commercialization and Distribution Agreement (the "Japan Distribution Agreement") with Nippon Shinyaku. Under the terms of the Japan Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in Japan of CAP-1002 for the treatment of DMD.

Under the terms of the Japan Distribution Agreement, Capricor received an upfront payment of $12.0 million in the first quarter of 2023 and in addition, Capricor will potentially receive additional development and sales-based milestone payments of up to approximately $89.0 million, subject to foreign currency exchange rates, and a meaningful double-digit share of product revenue. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in Japan. Capricor will be responsible for the conduct of clinical development in Japan, as may be required, as well as the manufacturing of CAP-1002. Subject to regulatory approval, Capricor will sell commercial product to Nippon Shinyaku in Japan. In addition, Capricor or its designee will hold the Marketing Authorization in Japan if the product is approved in that territory.

Financing Activities by the Company

September 2023 Financing

On September 29, 2023, the Company entered into Securities Purchase Agreements with its commercial partner, Nippon Shinyaku and funds associated with Highbridge Capital Management, LLC (the "Investors"), pursuant to which the Company agreed to issue and sell to the Investors, in a registered direct offering (the "Registered Direct Offering"), an aggregate of 4,935,621 shares of its common stock, par value $0.001 per share, at a price per share of $4.66 for an aggregate purchase price of approximately $23.0 million. Each share of common stock offered was sold with a warrant to purchase one share of common stock at an exercise price of $5.70 per share. Each warrant became exercisable beginning six months after issuance and will expire seven years from the date of issuance. As part of the Registered Direct Offering, the Company agreed not to issue or sell shares (subject to customary exceptions for employee stock option issuances and other customary exceptions) for a period of 30 days following the date of the prospectus supplement that was used in the Registered Direct Offering. That prospectus was dated September 29, 2023, and the Company "lock-up" expired on October 29, 2023. The Company's directors and executive officers also entered into "lock-up" agreements with the placement agent in the Registered Direct Offering, which agreements expired on the 60th day following the date of the Securities Purchase Agreements.

ATM Program

On June 21, 2021, the Company initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $75.0 million (the "ATM Program"), with the common stock to be distributed at the market prices prevailing at the time of sale. The ATM Program was established under a Common Stock Sales Agreement (the "Sales Agreement,"), with H.C. Wainwright & Co. LLC ("Wainwright"), under which we may, from time to time, issue and sell shares of our common stock through Wainwright as sales agent. The 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 ATM Program were issued pursuant to our shelf registration statement on Form S-3 (File No. 333-254363), which was initially filed with the Securities and Exchange Commission (the "SEC"), on March 16, 2021, amended on June 15, 2021 and declared effective by the SEC on June 16, 2021. From June 21, 2021 through May 13, 2024, the Company sold an aggregate of 3,588,506 shares of common stock under the ATM Program at an average price of approximately $5.61 per share for gross proceeds of approximately $20.1 million. Approximately $54.9 million of common stock may still be sold pursuant to the ATM Program. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to Wainwright, as well as legal and accounting fees in the aggregate amount of approximately $0.7 million.

CIRM Grant Award

On June 16, 2016, Capricor entered into an award (the "CIRM Award") with the California Institute for Regenerative Medicine ("CIRM") in the amount of approximately $3.4 million to fund, in part, Capricor's Phase 1/2 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 the CIRM Loan Policy and CIRM Grants Administration Policy for Clinical Stage Projects (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. Depending on the timing of our election, additional funds may be owed. 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 the amounts awarded by CIRM, therefore the Company accounts for this award as a liability rather than income.

In 2019, Capricor completed all milestones and close-out activities associated with the CIRM Award and expended all funds received. As of March 31, 2024, Capricor's liability balance for the CIRM Award was approximately $3.4 million.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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

ASC Topic 842, *Leases* ("ASC 842"), requires lessees to recognize most leases on the balance sheet with a corresponding right-to-use ("ROU") asset. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of fixed lease payments over the lease term. ROU assets are evaluated for impairment using the long-lived assets impairment guidance.

Leases will be classified as financing or operating, which will drive the expense recognition pattern. The Company elects to exclude short-term leases if and when the Company has them.

The Company leases office and laboratory space, all of which are operating leases. Most leases include the option to renew and the exercise of the renewal options is at the Company's sole discretion. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. In addition, the Company's lease agreements generally do not contain any residual value guarantees or restrictive covenants.

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.

For real estate leases, the Company has elected the practical expedient under ASC 842 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 for Contracts from Customers*, which amended revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries. The Company has not yet achieved commercial sales of its drug candidates to date, however, the new standard is applicable to its distribution agreements.

The revenue standard provides a five-step framework for recognizing revenue as control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that it determines are within the scope of the revenue standard, the Company performs the following five steps: (i) identify the contract; (ii) identify the performance obligations; (iii) determine the transaction price; (iv) allocate the transaction price to the performance

obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. At contract inception, the Company assesses whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation, or whether they are not distinct and are combined with other goods and services until a distinct bundle is identified. The Company then determines the transaction price, which typically includes upfront payments and any variable consideration that the Company determines is probable to not cause a significant reversal in the amount of cumulative revenue recognized when the uncertainty associated with the variable consideration is resolved. The Company then allocates the transaction price to each performance obligation and recognizes the associated revenue when, or as, each performance obligation is satisfied.

The Company's distribution agreements may entitle it to additional payments upon the achievement of milestones or shares of product revenue. The milestones are generally categorized into three types: development milestones, regulatory milestones and sales-based milestones. The Company evaluates whether it is probable that the consideration associated with each milestone or shared revenue payments will not be subject to a significant reversal in the cumulative amount of revenue recognized. Amounts that meet this threshold are included in the transaction price using the most likely amount method, whereas amounts that do not meet this threshold are excluded from the transaction price until they meet this threshold. At the end of each subsequent reporting period, the Company re-evaluates the probability of a significant reversal of the cumulative revenue recognized for its milestones and shared revenue payments, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and net income (loss) in the Company's condensed consolidated statements of operation and comprehensive loss. Typically, milestone payments and shared revenue payments are achieved after the Company's performance obligations associated with the distribution agreements have been completed and after the customer has assumed responsibility for the respective clinical program. Milestones or shared revenue payments achieved after the Company's performance obligations have been completed are recognized as revenue in the period the milestone or shared revenue payments was achieved. If a milestone payment is achieved during the performance period, the milestone payment would be recognized as revenue to the extent performance had been completed at that point, and the remaining balance would be recorded as deferred revenue.

The revenue standard requires the Company to assess whether a significant financing component exists in determining the transaction price. The Company performs this assessment at the onset of its distribution agreements. Typically, a significant financing component does not exist because the customer is paying for services in advance with an upfront payment. Additionally, future shared revenue payments are not substantially within the control of the Company or the customer.

Whenever the Company determines that goods or services promised in a contract should be accounted for as a combined performance obligation over time, the Company determines the period over which the performance obligations will be performed and revenue will be recognized. Revenue is recognized using either the proportional performance method or on a straight-line basis if efforts will be expended evenly over time. Percentage of completion of patient visits in clinical trials are used as the measure of performance. The Company feels this method of measurement to be the best depiction of the transfer of services and recognition of revenue. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations. If the Company determines that the performance obligation is satisfied over time, any upfront payment received is initially recorded as deferred revenue on its condensed consolidated balance sheets.

Certain judgments affect the application of the Company's revenue recognition policy. For example, the Company records short-term (less than one year) and long-term (over one year) deferred revenue based on its best estimate of when such revenue will be recognized. This estimate is based on the Company's current operating plan, and the Company may recognize a different amount of deferred revenue over the next 12-month period if its plan changes in the future.

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.

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 (“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 five 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"), (iv) the 2020 Equity Incentive Plan (the "2020 Plan"), and (v) the 2021 Equity Incentive Plan (the "2021 Plan"). At this time, the Company only issues options under the 2020 Plan and the 2021 Plan and no longer issues options under the 2006 Stock Option Plan, the 2012 Plan, or the 2012 Non-Employee Director Plan.

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

Stock options or other equity instruments to non-employees (including consultants) issued as consideration for goods or services received by us are accounted for based on the fair value of the equity instruments issued. The fair value of stock options is determined using the Black-Scholes option-pricing model. 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 conditions. 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 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, 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 condensed 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 discussions 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 condensed 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 October 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-06, Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative. This standard was issued in response to the SEC's disclosure update and simplification initiative, which affects a variety of topics within the Accounting Standards Codification. The amendments apply to all reporting entities within the scope of the affected topics unless otherwise indicated. The effective date for each amendment will be the date on which the SEC's

removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. The Company is currently evaluating the impact this guidance will have on its financial statement disclosures.

Other recent accounting pronouncements issued by the Financial Accounting Standards Board, 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, 2024, the fair value of our cash, cash equivalents and marketable securities was approximately $39.9 million. Additionally, as of March 31, 2024, Capricor's investment portfolio was classified as cash, cash equivalents and marketable securities, which consisted primarily of money market funds and bank money market, which included short-term 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 Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC'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 Exchange Act, 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, 2024 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.

Item 1A. Risk Factors.

Part 1, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on March 11, 2024, 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, 2023, as filed with the SEC on March 11, 2024.

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, 2024 formatted in Inline eXtensible Business Reporting Language (iXBRL): (i) Condensed Consolidated Balance Sheets as of March 31, 2024 and December 31, 2023, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity (Deficit), (iv) Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* 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, 2024

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

Date: May 14, 2024

By: /s/ Anthony J. Bergmann
Anthony J. Bergmann
Chief Financial Officer
(Principal Financial and Principal 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, 2024

/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, 2024

/s/ Anthony J. Bergmann
Name: Anthony J. Bergmann
Title: Chief Financial Officer, Principal Financial and Principal Accounting 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, 2024 (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, 2024

/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, 2024 (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, 2024

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