UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

☒ **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended June 30, 2025**

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 August 8, 2025, there were 45,716,975 shares of the registrant's common stock, par value $0.001 per share, issued and outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- how long we expect to maintain liquidity to fund our planned level of operations and our ability to obtain additional funds for our operations;
- the development of our drug and vaccine candidates, including when we expect to undertake, initiate and complete clinical trials of our drug and vaccine candidates;
- the expectation, plans, projections, initiation, timing, progress and results of our research and development programs, preclinical studies, any clinical trials, compassionate uses, Investigational New Drug filings, Clinical Trial Application filings, New Drug Application filings, Biologics License Application, and other regulatory submissions;
- regulatory developments involving products and our facilities, including the timing and results of regulatory meetings and inspections, and the ability to obtain regulatory approvals or otherwise bring products to market in both the United States and in countries outside of the United States;
- the impact of any reductions in force or changes in regulatory priorities at the U.S. federal agencies responsible for overseeing our industry;
- 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 designations for our lead product candidate, deramiocel (also referred to as CAP-1002);
- our use of clinical research centers, third party manufacturers and other contractors;
- our ability to manufacture and maintain sufficient inventories of our products to meet commercial demand;
- 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 at a cost that is acceptable to us;
- 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, including, but not limited to, those risks set forth under Part I, Item 1A, "Risk Factors" in the Company's most recent annual report on Form 10-K. Moreover, we operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report on Form 10-Q. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements. Additionally, final data may differ significantly from preliminary data reported in this document.

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

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

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements.

CAPRICOR THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

ASSETS

	June 30, 2025 (unaudited)	December 31, 2024
CURRENT ASSETS		
Cash and cash equivalents	$ 23,241,199	$ 11,286,996
Marketable securities	99,559,482	140,228,881
Receivables	59,509	10,368,489
Prepaid expenses and other current assets	1,266,356	1,500,901
TOTAL CURRENT ASSETS	124,126,546	163,385,267
PROPERTY AND EQUIPMENT, net	7,995,259	5,561,597
OTHER ASSETS		
Lease right-of-use assets, net	939,204	1,312,522
Other assets	508,002	221,700
TOTAL ASSETS	$ 133,569,011	$ 170,481,086
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 4,812,356	$ 3,283,712
Accrued expenses	7,359,232	4,907,665
Lease liabilities, current	849,505	834,799
CIRM liability, current	3,376,259	—
Deferred revenue, current	12,000,000	12,000,000
TOTAL CURRENT LIABILITIES	28,397,352	21,026,176
LONG-TERM LIABILITIES		
CIRM liability, net of current	—	3,376,259
Lease liabilities, net of current	194,603	616,315
TOTAL LONG-TERM LIABILITIES	194,603	3,992,574
TOTAL LIABILITIES	28,591,955	25,018,750
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, 100,000,000 shares authorized, 45,711,975 and 45,582,288 shares issued and outstanding, respectively	45,712	45,582
Additional paid-in capital	353,680,694	344,224,338
Accumulated other comprehensive income	1,387,574	1,026,955
Accumulated deficit	(250,136,924)	(199,834,539)
TOTAL STOCKHOLDERS' EQUITY	104,977,056	145,462,336
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 133,569,011	$ 170,481,086

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024	Six Months Ended June 30, 2025	Six Months Ended June 30, 2024
REVENUE				
Revenue	$ —	$ 3,971,438	$ —	$ 8,878,315
TOTAL REVENUE	—	3,971,438	—	8,878,315
OPERATING EXPENSES				
Research and development	22,047,254	12,504,769	40,962,826	23,605,782
General and administrative	5,671,880	3,057,888	11,739,256	7,129,654
TOTAL OPERATING EXPENSES	27,719,134	15,562,657	52,702,082	30,735,436
LOSS FROM OPERATIONS	(27,719,134)	(11,591,219)	(52,702,082)	(21,857,121)
OTHER INCOME (EXPENSE)				
Other income	14,991	—	27,476	—
Investment income	1,793,352	591,437	2,522,894	1,063,266
Loss on disposal of fixed assets	—	—	(150,673)	—
TOTAL OTHER INCOME (EXPENSE)	1,808,343	591,437	2,399,697	1,063,266
NET LOSS	(25,910,791)	(10,999,782)	(50,302,385)	(20,793,855)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	(424,353)	(152,714)	360,619	(80,826)
COMPREHENSIVE LOSS	$ (26,335,144)	$ (11,152,496)	$ (49,941,766)	$ (20,874,681)
Net loss per share, basic and diluted	$ (0.57)	$ (0.35)	$ (1.10)	$ (0.66)
Weighted average number of shares, basic and diluted	45,709,071	31,841,964	45,673,075	31,598,296

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance at December 31, 2024	45,582,288	$ 45,582	$ 344,224,338	$ 1,026,955	$ (199,834,539)	$ 145,462,336
Exercise of common warrants	699	1	3,983	—	—	3,984
Stock-based compensation	—	—	5,481,938	—	—	5,481,938
Vesting of restricted stock awards	17,210	17	257,444	—	—	257,461
Stock options exercised	76,690	77	46,293	—	—	46,370
Unrealized gain on marketable securities	—	—	—	784,972	—	784,972
Net loss					(24,391,594)	(24,391,594)
Balance at March 31, 2025	45,676,887	$ 45,677	$ 350,013,996	$ 1,811,927	$ (224,226,133)	$ 127,645,467
Stock-based compensation	—	—	3,647,153	—	—	3,647,153
Stock options exercised	35,088	35	19,545	—	—	19,580
Unrealized loss on marketable securities	—	—	—	(424,353)	—	(424,353)
Net loss	—	—	—	—	(25,910,791)	(25,910,791)
Balance at June 30, 2025	45,711,975	$ 45,712	$ 353,680,694	$ 1,387,574	$ (250,136,924)	$ 104,977,056

	COMMON STOCK SHARES	COMMON STOCK AMOUNT	ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
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 gain 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
Issuance of common stock, net of fees	330,458	331	1,985,518	—	—	1,985,849
Stock-based compensation	—	—	2,152,793	—	—	2,152,793
Stock options exercised	53,286	53	81,169	—	—	81,222
Unrealized loss on marketable securities	—	—	—	(152,714)	—	(152,714)
Net loss	—	—	—	—	(10,999,782)	(10,999,782)
Balance at June 30, 2024	31,983,927	$ 31,984	$ 191,476,543	$ 154,987	$ (180,161,208)	$ 11,502,306

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Six months ended June 30, 2025	Six months ended June 30, 2024
Cash flows from operating activities:		
Net loss	$ (50,302,385)	$ (20,793,855)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	150,673	—
Depreciation and amortization	891,728	688,341
Stock-based compensation	9,129,091	5,418,205
Restricted stock awards granted	257,461	—
Changes in lease liabilities	(33,688)	(20,199)
Changes in operating assets and liabilities:		
Receivables	10,308,980	10,002,018
Prepaid expenses and other current assets	198,243	107,172
Accounts payable and accrued expenses	2,844,166	(80,307)
Deferred revenue	—	(8,878,314)
Net cash used in operating activities	(26,555,731)	(13,556,939)
Cash flows from investing activities:		
Purchase of marketable securities	(78,177,790)	(49,283,647)
Proceeds from sales and maturities of marketable securities	119,207,807	55,222,000
Purchases of property and equipment	(1,183,745)	(668,928)
Payments for leasehold improvements	(375,008)	(76,295)
Payments for construction in progress	(1,031,264)	—
Net cash provided by investing activities	38,440,000	5,193,130
Cash flows from financing activities:		
Net proceeds from sale of common stock	—	4,276,093
Proceeds from exercise of stock awards and warrants	69,934	81,222
Net cash provided by financing activities	69,934	4,357,315
Net increase (decrease) in cash and cash equivalents	11,954,203	(4,006,494)
Cash and cash equivalents balance at beginning of period	11,286,996	14,694,857
Cash and cash equivalents balance at end of period	$ 23,241,199	$ 10,688,363
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 (together with its wholly-owned subsidiary, 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. Capricor became public after the completion of a merger between Capricor and a subsidiary of Nile Therapeutics, Inc., a Delaware corporation ("Nile"), in 2013, where Capricor became a wholly-owned subsidiary of Nile and Nile formally changed its name to Capricor Therapeutics, Inc. Capricor Therapeutics was listed on the Nasdaq Capital Market shortly thereafter. 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 26, 2025, from which the December 31, 2024 consolidated balance sheet was derived. Interim results are not necessarily indicative of the results that may be expected for the year ending December 31, 2025.

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 Capital Resources

As of June 30, 2025, the Company's cash, cash equivalents and marketable securities totaled approximately $122.8 million with an accumulated deficit of approximately $250.1 million. The Company has historically financed its research and development activities as well as operational expenses primarily from equity financings and payments from collaboration partners. The Company's principal uses of cash are for research and development expenses, expenses in development of manufacturing capabilities, 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, commercial launch activities, clinical trials and preclinical studies;
- 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 deramiocel for DMD in the United States and other select territories;
- the timing and costs associated with potential commercialization of our product candidates, including costs associated with responding to regulatory requests and related matters;
- the number and scope of our research programs, including the expansion of our exosomes program;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights;
- the costs associated with pursuing marketing approval and potential commercialization of deramiocel in countries outside the United States; and
- the timing and costs involved in defending lawsuits filed against the Company.

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 potentially from government grants. The Company has incurred significant operating losses and negative cash flows from operations.

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 trials and research and development programs. To the extent the Company issues additional equity securities, its existing stockholders would experience substantial dilution.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. 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 June 30, 2025, 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 $486,278 and $356,935 for the three months ended June 30, 2025 and 2024, respectively, and $891,728 and $688,341 for the six months ended June 30, 2025 and 2024, respectively.

Property and equipment, net consisted of the following:

	June 30, 2025	December 31, 2024
Furniture and fixtures	$ 189,821	$ 192,083
Laboratory equipment	7,334,478	6,318,362
Leasehold improvements	2,776,864	2,501,207
Construction in progress	1,851,712	—
	12,152,875	9,011,652
Less accumulated depreciation	(4,157,616)	(3,450,055)
Property and equipment, net	$ 7,995,259	$ 5,561,597

Long-Lived Assets

The Company accounts for the impairment and disposition of long-live assets in accordance with guidance issued by the Financial Accounting Standards Board ("FASB"). Long-lived assets to be held and used are reviewed for events or changes in circumstances that indicate that their carrying value may not be recoverable, or annually. No impairment related to long-lived assets was recorded for the three and six months ended June 30, 2025 and 2024.

Cloud Computing Arrangements

The Company's cloud computing arrangements ("CCA") primarily relate to its enterprise resource planning system. Capitalized implementation costs associated with these arrangements are included in prepaid expenses and other current assets and other assets on the condensed consolidated balance sheets and are amortized on a straight-line basis over their estimated useful life of seven years. As of June 30, 2025, capitalized implementation costs totaled $306,783, with no accumulated amortization recognized, as the system had not yet been placed in service. There were no capitalized CCA assets as of December 31, 2024.

Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2025	December 31, 2024
Accrued clinical expenses	$ 1,830,559	$ 1,919,437
Accrued payroll and related costs	4,078,974	2,552,516
Other accrued expenses	1,449,699	435,712
Total accrued expenses	$ 7,359,232	$ 4,907,665

Leases

Accounting Standards Codification ("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 from ASC 842 analysis 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 recognizes revenue following a five-step framework 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 by: (i) identifying the contract; (ii) identifying the performance obligations; (iii) determining the transaction price; (iv) allocating the transaction price to the performance obligations in the contract; and (v) recognizing 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 two types: development 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 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 operating plan changes in the future.

Under the U.S. Commercialization and Distribution Agreement (the "U.S. Distribution Agreement") with Nippon Shinyaku Co., Ltd., a Japanese corporation ("Nippon Shinyaku"), the transaction price consists of variable shared revenue payments and fixed components in the form of an upfront payment and milestones. For the first performance obligation identified, which is the conduct of the HOPE-3, Phase 3 clinical study, 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 the first milestone, a contract liability is recorded which represents deferred revenue. The Company evaluates the measure of progress for each reporting period and, if necessary, adjusts the related revenue recognition. For the second performance obligation identified, which is the submission of our BLA to the FDA, the payment was due at the point in time when the application was submitted in December 2024. As such, revenue was recognized at the point in time, and a contract asset was recorded which represents accounts receivable.

Receivables

As of June 30, 2025, receivables primarily consisted of $59,166 related to funds due from the Employee Retention Credit. As of December 31, 2024, accounts receivable primarily consisted of $10.0 million due from Nippon Shinyaku, related to the second milestone payment, as well as $366,551 related to funds due from the Employee Retention Credit.

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 $22.0 million and $12.5 million for the three months ended June 30, 2025 and 2024, respectively, and approximately $41.0 million and $23.6 million for the six months ended June 30, 2025 and 2024, 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 $26.3 million and $11.2 million for the three months ended June 30, 2025 and 2024, respectively, and approximately $49.9 million and $20.9 million for the six months ended June 30, 2025 and 2024, respectively. The Company's other comprehensive income (loss) is related to net unrealized gain (loss) on marketable securities. The

Company's other comprehensive income (loss) was $(424,353) and $(152,714) for the three months ended June 30, 2025 and 2024, respectively, and $360,619 and $(80,826) for the six months ended June 30, 2025 and 2024, 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.

For stock options, the Company estimates the fair value of the 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.

For restricted stock awards, the Company determines the fair value using the Company's adjusted closing stock price on the grant date.

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 and six months ended June 30, 2025 and 2024, warrants and options to purchase 17,704,007 and 15,631,881 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 and six months ended June 30, 2025 and 2024.

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 June 30, 2025 and December 31, 2024 for assets and liabilities measured at fair value on a recurring basis:

	June 30, 2025			
	Level I	Level II	Level III	Total
Marketable Securities	$ 99,559,482	$ —	$ —	$ 99,559,482

	December 31, 2024			
	Level I	Level II	Level III	Total
Marketable Securities	$ 140,228,881	$ —	$ —	$ 140,228,881

Carrying amounts reported in the balance sheet of cash and cash equivalents, receivables, prepaid expenses and other current assets, accounts payable, accrued expenses, and deferred revenue 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.

Segment Information

The Company operates as a single segment because its chief operating decision maker review operating results on an aggregate basis and manage its operations as a single operating segment.

Recent Accounting Pronouncements

In November 2024, the FASB issued ASU No. 2024-03, Disaggregation of Income Statement Expenses (Subtopic 220-40). The ASU requires the disaggregated disclosure of specific expense categories, including purchases of inventory, employee compensation, depreciation and amortization, within relevant income statement captions. This ASU also requires disclosure of the total amount of selling expenses along with the definition of selling expenses. The ASU is effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Adoption of this ASU can either be applied prospectively to consolidated financial statements issued for reporting periods after the effective date of this ASU or retrospectively to any or all prior periods presented in the consolidated financial statements. Early adoption is also permitted. This ASU will likely result in the required additional disclosures being included in our consolidated financial statements once adopted. 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. STOCKHOLDERS' EQUITY

October 2024 Underwritten Public Offering

On October 16, 2024, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Piper Sandler and Oppenheimer as representatives of the underwriters (the "Underwriters"), pursuant to which the Company agreed to sell and issue, in a public offering, an aggregate of 5,073,800 shares of common stock, including the exercise in full of the underwriters' option to purchase additional shares to cover over allotments, at a public offering price of $17.00 per share for total gross proceeds of approximately $86.3 million, before deducting underwriting commissions and other offering expenses payable by the Company. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to the Underwriters, as well as legal and accounting fees in the aggregate amount of approximately $5.4 million.

September 2024 Private Placement

On September 16, 2024, the Company entered into a Subscription Agreement with Nippon Shinyaku pursuant to which the Company agreed to issue and sell to Nippon Shinyaku in a private placement (the "Private Placement"), an aggregate of 2,798,507 shares of the common stock of the Company at a price per Share of $5.36, which was issued at a 20% premium to the 60-day volume-weighted average price, for an aggregate purchase price of approximately $15.0 million. The Subscription Agreement also included lock-up provisions restricting Nippon Shinyaku from selling or otherwise disposing of shares of the Company's common stock until the six-month anniversary of the Closing Date which occurred on March 15, 2025.

In connection with the Private Placement, the Company also entered into a Registration Rights Agreement with Nippon Shinyaku on September 16, 2024 (the "Registration Rights Agreement"). Pursuant to the terms of the Registration Rights Agreement, the Company has filed with the SEC a registration statement to register for resale the shares sold in the Private Placement, which registration statement was declared effective on November 8, 2024.

ATM Program

The Company established an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $75.0 million (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 H.C. Wainwright & Co. LLC ("Wainwright") by which Wainwright sold our common stock at the market prices prevailing at the time of sale. Wainwright was entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold plus reimbursement of certain expenses.

From June 21, 2021 through October 1, 2024, the Company sold an aggregate of 9,228,383 shares of common stock under the ATM Program at an average price of approximately $8.13 per share for gross proceeds of approximately $75.0 million which represents all amounts that were available to be sold under the ATM program. Effective October 1, 2024, the ATM Program was closed and terminated. 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 $2.4 million.

3. STOCK AWARDS, WARRANTS AND OPTIONS

Warrants

The following table summarizes all warrant activity for the six months ended June 30, 2025:

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2024	4,935,621	$ 5.70
Granted	—	—
Exercised	(699)	5.70
Outstanding at June 30, 2025	4,934,922	$ 5.70

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

		Warrants Outstanding			
Type	Grant Date	June 30, 2025	December 31, 2024	Exercise Price per Share	Expiration Date
Common Warrants	10/3/2023	4,934,922	4,935,621	$ 5.70	10/3/2030
		4,934,922	4,935,621		

Stock Awards

The Company's Board of Directors (the "Board") has approved six 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"), (v) the 2021 Equity Incentive Plan (the "2021 Plan"), and (vi) the 2025 Equity Incentive Plan (the "2025 Plan"). At this time, the Company only issues stock options and restricted stock awards under the 2020 Plan, the 2021 Plan, and the 2025 Plan and no longer issues stock awards 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 was 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, 2025 and 2024, 2,279,114 and 1,557,416 shares were added under the 2021 Plan, respectively. Once the 2025 Plan was approved on May 22, 2025, no new shares have been or will be added to the share reserve under the 2021 Plan.

In May 2025, the Company's stockholders approved the 2025 Plan, which authorized 3,500,000 shares of common stock reserved under the 2025 Plan for the issuance of stock awards. The number of shares available for issuance under the 2025 Plan shall be automatically increased on January 1 of each year, commencing with January 1, 2026 and ending on January 1, 2035, by an amount equal to 5% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year.

As of June 30, 2025, 3,634,646 shares 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 award granted will be designated in the award agreement as either an incentive stock option, a nonstatutory stock option, or a restricted stock award. 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.

Stock Option Awards

The estimated weighted average fair value of the options granted during the three months ended June 30, 2025 and 2024 were approximately $10.59 and $4.18 per share, respectively. The estimated weighted average fair value of the options granted during the six months ended June 30, 2025 and 2024 were approximately $12.33 and $4.57 per share, respectively.

The Company estimates the fair value of each option award using the Black-Scholes option-pricing model. The company used the following assumptions to estimate the fair value of stock options issued during the six months ended June 30, 2025 and 2024:

	Six months ended June 30,	
	2025	2024
Expected volatility	112 - 115 %	109 - 119 %
Expected term	5 - 6 years	5 - 7 years
Dividend yield	0 %	0 %
Risk-free interest rates	3.9 - 4.5 %	3.9 - 4.3 %

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

	Three months ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
General and administrative	$ 1,716,687	$ 1,300,321	$ 4,717,501	$ 3,578,006
Research and development	1,930,466	852,472	4,669,051	1,840,199
Total	$ 3,647,153	$ 2,152,793	$ 9,386,552	$ 5,418,205

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.

As of June 30, 2025, the total unrecognized fair value compensation cost related to non-vested stock options was approximately $37.9 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 six months ended June 30, 2025:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2024	10,731,183	$ 4.38	
Granted	2,415,527	14.49	
Exercised	(149,206)	3.27	$ 1,330,081
Expired/Cancelled	(228,419)	9.96	
Outstanding at June 30, 2025	12,769,085	$ 6.20	$ 60,573,390
Exercisable at June 30, 2025	7,660,232	$ 4.09	$ 46,507,669

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.

Restricted Stock Awards

The Company has granted restricted stock awards ("RSAs") under the 2021 Plan. The stock awards are fully vested upon grant and each outstanding RSA will be exchanged for one share of the Company's common stock. The Company estimates the fair value of each restricted stock award using the Company's adjusted closing stock price on the grant date.

The following table summarized the activity of the Company's RSA for the six months ended June 30, 2025:

	Number of RSAs	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2024	—	$ —
Granted	17,210	14.96
Vested	(17,210)	14.96
Expired/Cancelled	—	—
Outstanding at June 30, 2025	—	$ —

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 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 I/II HOPE-Duchenne clinical trial investigating deramiocel 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 potentially 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 could have been required to pay to CIRM was 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 had 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. In 2019, Capricor completed all milestones and close-out activities associated with the CIRM Award and expended all funds received.

The Company accounts for this award as a liability rather than income. As of June 30, 2025, Capricor’s principal liability balance for the CIRM Award was approximately $3.4 million, excluding any accrued interest.

On February 26, 2025, Capricor notified CIRM of its election to convert the CIRM Award into a loan. As a result, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements. The terms of the loan agreement are currently under discussion with CIRM. Depending on the results of these discussions, accrued interest on the CIRM Award could reach up to approximately $7.1 million and may continue to accrue over time until the final payout. There was no accrued interest recorded as of June 30, 2025.

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. Effective July 1, 2023, the monthly lease payment was $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 were granted an exclusive license to use certain space and the non-exclusive right to use certain equipment and property for our early phase clinical manufacturing purposes. Our license fee was approximately $110,615 per month. The initial license agreement term expired on September 26, 2024, which the Company extended through November 8, 2024.

Commencing on November 20, 2024, the Company entered into a lease with Shiraz Partners LP for manufacturing facilities located in Vista, California, with a term of 6 months with an option to extend for another 6 months. The monthly base rent is $31,247. In March 2025, the Company extended the term of the lease to November 19, 2025, with an increased monthly base rent of $41,247 beginning May 21, 2025.

In December 2024, the Company entered into a sublease agreement with Entos Pharmaceuticals US, Inc. for office and research space located in San Diego, California, with a monthly base rent of $63,127. The lease has a term of 12 months and has an option to continue on a month-to month basis after the expiration date.

Expenses incurred under short-term operating leases for the three months ended June 30, 2025 and 2024 were $353,298 and $354,703, respectively, and $722,476 and $447,617 for the six months ended June 30, 2025 and 2024. Short-term operating lease payments for the three months ended June 30, 2025 and 2024 were $335,970 and $380,357, respectively, and $705,148 and $764,714 for the six months ended June 30, 2025 and 2024.

Long-Term Operating Leases

Capricor leases facilities in Los Angeles, California from CSMC, pursuant to a lease (the “Facilities Lease”) entered into in 2014. Capricor subsequently entered into several amendments modifying certain terms of the lease. We entered into an amendment effective August 1, 2024 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 for an additional term of five years. The Company subsequently entered into several amendments to the San Diego Lease increasing the square footage of the premises. Effective October 1, 2023, the monthly lease payment was increased to $58,409 per month. Effective October 1, 2024, the monthly lease payment was increased to $60,161 per month. On February 26, 2025, the Company entered into a fourth lease amendment with Altman (the "Fourth Amendment"). Pursuant to the terms of the Fourth Amendment, the Company increased the rentable square footage to 34,348 square feet commencing on or before July 1, 2025 and extended the lease term to September 30, 2033. Commencing January 1, 2026, the base rent will increase to $188,914 per month. The rent is subject to a 3.0% annual rent increase commencing October 1, 2026 plus certain operating expenses and taxes. The Fourth Amendment contains an option for Capricor to renew for an additional term of five years. The Fourth Amendment commenced on July 1, 2025, and the Company estimates the amendment will result in an increase of approximately $13.5 million in operating lease liabilities and $13.4 million in right-of-use assets in the third quarter of 2025.

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 subject to 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 sheets 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 sheets.

The table below excludes short-term operating leases. The following table summarizes maturities of lease liabilities and the reconciliation of lease liabilities as of June 30, 2025:

2025 (remainder)	$	459,818
2026		634,888
2027		—
2028		—
2029		—
Total minimum lease payments		1,094,706
Less: imputed interest		(50,598)
Total operating lease liabilities	$	1,044,108
Included in the consolidated balance sheet:		
Current portion of lease liabilities	$	849,505
Lease liabilities, net of current		194,603
Total operating lease liabilities	$	1,044,108
Other Information:		
Weighted average remaining lease term		1.2 years
Weighted average discount rate		7.4%

The following table contains a summary of the lease costs recognized and lease payments pertaining to the Company's operating leases under ASC 842 for the period indicated:

	Three months ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Lease costs	$ 210,357	$ 210,357	$ 420,714	$ 420,714
Lease payments	227,201	229,197	454,403	455,822

Legal Contingencies

On July 17, 2025 a putative securities class action was filed in the Southern District of California, naming Capricor Therapeutics, Inc. and our chief executive officer, Linda Marbán. The action alleges certain violations of the U.S. federal securities laws and seeks unspecified damages.

On August 1, 2025 a derivative action was filed in the Southern District of California naming each of the Directors on the Board of Capricor Therapeutics, Inc. The action alleges, among other things, breaches of fiduciary duties and seeks unspecified damages.

In addition, from time to time, the Company may become involved in various other 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 June 30, 2025.

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, subject to certain time periods, 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 from time to time may approve severance packages for specific full-time employees based on their length of service and position ranging up to twelve 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 June 30, 2025.

7. LICENSE AND DISTRIBUTION AGREEMENTS

Intellectual Property Rights for Capricor's Technology - Deramiocel 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 Cedars-Sinai Medical Center ("CSMC"). Capricor is also a party to an exclusive license agreement for intellectual property rights related to exosomes with CSMC. In addition, Capricor has filed patent applications related to the technology developed by its own scientists.

University of Rome License Agreement

Capricor and the University of Rome entered into a License Agreement, dated June 21, 2006 (the "Rome License Agreement"), which provides for the grant of an exclusive, world-wide, royalty-bearing license by the University of Rome to Capricor (with the right to sublicense) to develop and commercialize licensed products under the licensed patent rights in all fields.

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 the Rome License Agreement for any reason upon 90 days' written notice to the University of Rome.

The Johns Hopkins University License Agreement

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 license 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 FDA. The maximum aggregate amount of milestone payments payable under the JHU License Agreement, as amended, is $1,850,000. In March 2022, Capricor paid the $250,000 development milestone related to the Phase 2 study pursuant to the terms of the JHU License Agreement. Capricor's next milestone payments will be triggered, if at all, upon a successful completion of a full Phase 3 study, for which a payment of $500,000 will be due, and upon receipt of a full FDA market approval, for which a payment of $1,000,000 will be due (and either milestone may occur before the other).

The JHU License Agreement will, unless sooner terminated, continue in effect in each applicable country until the date of expiration of the last to expire patent within the patent rights, or, if no patents are issued, then for twenty years from the effective date. Under the terms of the JHU License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy or fail to cure a material breach within 30 days after notice. In addition, Capricor may terminate for any reason upon 60 days' written notice.

Cedars-Sinai Medical Center License Agreements

License Agreement for CDCs

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

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

Pursuant to the Original CSMC License Agreement, CSMC was paid a license fee and Capricor was obligated to reimburse CSMC for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor is required to meet certain spending and development milestones.

Pursuant to the Amended CSMC License Agreement, Capricor remains obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a low double-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third party for patent rights in connection with the royalty-bearing product.

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.

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.

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 and related party (see Note 8 – "Related Party Transactions"). Under the terms of the U.S. Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in the United States of deramiocel for the treatment of DMD.

Nippon Shinyaku and NS Pharma, Inc. (its wholly-owned U.S. subsidiary) will be responsible for the distribution of deramiocel in the United States. Pursuant to the U.S. Distribution Agreement, Capricor received an upfront payment of $30.0 million in 2022. The first milestone payment of $10.0 million was paid upon completion of the futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. The second milestone payment of $10.0 million was triggered in December 2024 upon submission of the BLA to the FDA seeking marketing approval of deramiocel in the United States. Additionally, there is another potential milestone of $80.0 million due to Capricor upon receipt of marketing approval. The foregoing milestones are considered development milestones under the terms of the U.S. Distribution Agreement. Further, there are various potential sales-based milestones, if commercialized, tied to the achievement of certain sales thresholds for annual net sales of deramiocel of up to $605.0 million. Subject to regulatory approval, Capricor will have the right to receive a share of product revenue which falls between 30 and 50 percent.

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 first milestone payment of $10.0 million. The Company has excluded any future milestone or shared revenue payments from this transaction price to date based on probability. Revenue related to this performance obligation has been 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. As of December 31, 2024, all of the $40.0 million has been recognized as revenue.

In December 2024, the Company triggered its second milestone with Nippon Shinyaku under the U.S. Distribution Agreement, which related to a separate distinct performance obligation. The performance obligation was tied to the submission of our BLA to the FDA. As a result, the $10.0 million milestone payment was recognized as revenue within the Company's consolidated statement of operations and comprehensive loss as of December 31, 2024.

In relation to the U.S. Distribution Agreement, for the three and six months ended June 30, 2025, the Company did not recognize any revenue compared to approximately $4.0 million and $8.9 million of revenue recognized for the three and six months ended June 30, 2024, respectively. There was no deferred revenue recorded as of June 30, 2025 or December 31, 2024. As of December 31, 2024, the Company recognized a receivable of $10.0 million related to the second milestone, which payment was received in January 2025.

The Company had no opening or closing contract asset balances recognized other than the accounts receivable mentioned above. 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.

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 deramiocel 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 deramiocel in Japan. Capricor will be responsible for the conduct of clinical development and regulatory approval in Japan, as may be required, as well as the manufacturing of deramiocel. 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 June 30, 2025.

Binding Term Sheet with Nippon Shinyaku (Territory: European Region)

On September 16, 2024, Capricor entered into a Binding Term Sheet (the "Term Sheet") with Nippon Shinyaku for the commercialization and distribution of deramiocel for the treatment of DMD in the European region, as defined in the Term Sheet. Subject to finalization of a definitive agreement, under the terms of the Term Sheet, Capricor would be responsible for the development and manufacturing of deramiocel for potential approval in the European region. Nippon Shinyaku would be responsible for the sales and distribution of deramiocel in the European region. Subject to regulatory approval, Capricor would receive a double-digit share of product revenue and additional development and sales-based milestone payments. If the definitive agreement is entered into on the same economic terms as the term sheet, Capricor will receive an upfront payment of $20.0 million upon execution of the definitive agreement, with potential additional development and sales-based milestone payments of up to $715.0 million. Upon execution of the definitive agreement, the Company will evaluate the terms in accordance with ASU 606, *Revenue for Contracts from Customers*. As of June 30, 2025, nothing has been recorded or received.

Capricor and Nippon Shinyaku have entered into several amendments to the Term Sheet, pursuant to which the parties agreed to extend the date during which the parties are obligated to continue to negotiate in good faith toward a definitive agreement to September 30, 2025.

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 June 30, 2025 and December 31, 2024, $10,000 was recorded in accounts payable 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 whereby he was granted an option to purchase 30,000 shares of the Company's common stock.

Commercialization and Distribution Agreements

As noted above, Capricor is party to two commercialization and distribution agreements with Nippon Shinyaku, which holds more than 10% of the outstanding capital stock of Capricor Therapeutics (see Note 7 – "License and Distribution Agreements"). There were no outstanding receivables or payables as of June 30, 2025.

Binding Term Sheet

As noted above, on September 16, 2024, Capricor entered into the Term Sheet with Nippon Shinyaku for the commercialization and distribution of deramiocel for the treatment of DMD in the European region, as defined in the Term Sheet (see Note 7 – "License and Distribution Agreements").

Private Placement

On September 16, 2024, the Company entered into a Subscription Agreement with Nippon Shinyaku pursuant to which the Company agreed to issue and sell to Nippon Shinyaku in the Private Placement, an aggregate of 2,798,507 shares of the common stock of the Company at a price per Share of $5.36, which was issued at a 20% premium to the 60-day volume-weighted average price, for an aggregate purchase price of approximately $15.0 million. In connection with the Private Placement, the Company also entered into the Registration Rights Agreement. Pursuant to the terms of the Registration Rights Agreement, the Company filed with the SEC a registration statement to register for resale the shares sold in the Private Placement, which registration statement was declared effective on November 8, 2024.

9. SUBSEQUENT EVENTS

The Company has evaluated subsequent events occurring after the balance sheet date through August 11, 2025, the date the financial statements were authorized for issuance. Based on this evaluation, and as described in Note 6 –"Commitments and Contingencies", the Company has determined that there are no other subsequent events that require adjustment to or disclosure in the financial statements.

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, and the audited consolidated financial statements and notes and Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in the Company's most recent annual report on Form 10-K. This discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including, but not limited to, those set forth under Part I, Item 1A, "Risk Factors" in the Company's most recent annual report on Form 10-K and under the heading "Special Note Regarding Forward-Looking Statements" in this Quarterly Report, 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 deramiocel and our other product candidates including our exosomes platform technology, developing our manufacturing processes, staffing our company and providing general and administrative support for these operations. We do not have any products approved for commercial sale. Our ability to eventually generate any product revenue sufficient to achieve profitability will depend on the successful development, approval and eventual commercialization of deramiocel for the treatment of DMD and our other product candidates. If successfully developed and approved, we intend and plan to commercialize deramiocel in the United States and Japan with our partner, Nippon Shinyaku Co., Ltd., a Japanese corporation (Nippon Shinyaku). Capricor 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, 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:

Deramiocel for the Treatment of DMD: Regulatory and Clinical Update

Capricor's lead clinical program is centered on deramiocel, an allogeneic cell therapy comprised of cardiosphere-derived cells (CDCs), for the treatment of cardiomyopathy associated with Duchenne muscular dystrophy. CDCs are a unique population of cardiac cells derived from healthy donor hearts, and they exert their therapeutic effect through immunomodulatory, anti-inflammatory, pro-angiogenic, and anti-fibrotic mechanisms—primarily mediated by secreted exosomes enriched with bioactive microRNAs. These non-coding RNA species influence gene expression in immune and tissue-resident cells, promoting regeneration and reducing inflammation, in contrast to dystrophin-restoring approaches like exon-skipping or gene therapy.

DMD is a progressive, fatal genetic disorder that results in significant skeletal and cardiac muscle deterioration. Over time, the lack of functional dystrophin leads to cardiomyocyte death and fibrosis, ultimately progressing to heart failure—the leading cause of death in DMD patients. There are currently no approved therapies specifically targeting DMD-associated cardiomyopathy, representing a substantial unmet medical and commercial opportunity for deramiocel.

Regulatory Progress and BLA Pathway

In the third quarter of 2024, we conducted a pre-Biologics License Application (BLA) meeting with the U.S. Food and Drug Administration (FDA) to discuss key components of our submission strategy, including the use of data from our HOPE-2 and HOPE-2 open label extension (OLE) trials, commercial manufacturing readiness and potential label considerations. Following additional discussions with the FDA, we completed our rolling BLA submission in December 2024. In early 2025, the FDA accepted our application for review, granted it Priority Review, and assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 31, 2025.

At the May 2025 mid-cycle review meeting, the FDA noted no significant deficiencies. In May 2025, the FDA conducted a Pre-License Inspection (PLI) of our San Diego manufacturing facility for deramiocel. The inspection concluded with a Form 483 containing several observations. We were recently informed by the FDA that they have reviewed and found acceptable all responses to the 483 observations noted in the PLI.

In July 2025, we received a Complete Response Letter (CRL) stating that the current BLA does not meet the statutory requirement for substantial evidence of effectiveness and the need for additional clinical data. The CRL also cited certain outstanding items in the Chemistry, Manufacturing, and Controls (CMC) section, many of which we had previously addressed but were not reviewed by the FDA due to timing of the issuance of the CRL. At this time, we have internally addressed the remaining CMC issues noted in the CRL and have prepared formal responses which we plan to submit with our response to the CRL.

We are now actively preparing a formal written response to the CRL and have scheduled a Type A meeting with the FDA for August 2025. Pending regulatory guidance, Capricor seeks to resubmit its BLA based on its existing dataset and with HOPE-3 data (expected to be available in the fourth quarter of 2025) potentially serving as supportive and confirmatory evidence.

Clinical Development Overview

To date, we have completed two clinical trials evaluating deramiocel in DMD patients. The Phase I/II HOPE-Duchenne study showed encouraging signals in both skeletal and cardiac endpoints. In our randomized, placebo-controlled Phase II HOPE-2 trial, deramiocel met its primary endpoint (mid-level PUL v1.2; p=0.01) and secondary endpoints, including full PUL v2.0 (p=0.04) and left ventricular ejection fraction (LVEF; p=0.002). These results were published in The Lancet in March 2022, and the therapy was generally safe and well-tolerated.

Building on these results, we initiated the HOPE-2 OLE study, in which, at this time, 12 patients are continuing treatment with deramiocel. In June 2025, we reported positive four-year outcomes in the HOPE-2 OLE study demonstrating sustained preservation of cardiac function and a slowing in skeletal muscle decline. These findings further underscore the potential of deramiocel to alter disease progression. Clinical benefit was also observed when comparing treated patients to a natural history cohort, including statistically significant differences in PUL v2.0 scores and cardiac function metrics.

Phase 3 HOPE-3 Clinical Trial and Next Steps

Our ongoing Phase 3 clinical trial, HOPE-3, is a 1:1 randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of deramiocel in approximately 104 boys with DMD. Participants receive four doses over 12 months, and the trial includes two manufacturing cohorts: Cohort A (Los Angeles facility) and Cohort B (San Diego facility). In the fourth quarter of 2023, the Data Safety Monitoring Board (DSMB) reviewed a pre-specified futility analysis and recommended that the study continue as planned.

We recently completed the 12-month treatment period in HOPE-3 and expect to report topline results in the fourth quarter of 2025, although the study remains blinded at present. In alignment with FDA feedback and our evolving regulatory strategy, we amended the study protocol to designate LVEF as the primary endpoint, shifting the focus to cardiac efficacy. This change reflects the FDA's emphasis on well-controlled cardiac outcome measures in DMD based on FDA feedback in the CRL and may, if the results are positive and accepted by the FDA, meaningfully support our BLA. Skeletal muscle function will remain a key secondary endpoint, assessed via PUL v2.0, which captures upper limb strength across a spectrum of functional domains.

Additionally, if positive, HOPE-3 may support international regulatory filings, and we have initiated discussions with health authorities in Europe and Japan to define potential approval pathways.

Designations and Commercial Planning

Deramiocel has received RMAT and orphan drug designations, and, if approved, Capricor is eligible to receive a Priority Review Voucher (PRV) under its rare pediatric disease designation. Capricor retains full rights to the PRV, if granted.

We have entered into exclusive Commercialization and Distribution Agreements with Nippon Shinyaku for the United States and Japan. We aim to efficiently scale commercial efforts in key markets upon potential approval.

Exosome Platform

Extracellular vesicles, including exosomes and microvesicles, are nanoscale, membrane-enclosed particles secreted by most cells. These vesicles carry proteins, lipids, and nucleic acids (such as mRNA and microRNAs) and play a key role in intercellular communication. They signal by binding to membrane receptors or delivering their cargo directly into target cells, influencing functions such as inflammation, survival, proliferation, and tissue regeneration. Due to their small size, low immunogenicity, and ability to interact in native cellular language, exosomes represent a promising new class of therapeutic agents capable of modulating complex biological systems. As cell-free products, they offer advantages in storage, handling, and delivery similar to traditional biologics like monoclonal antibodies.

Our focus is on developing a precision engineered exosome platform capable of delivering defined sets of effector molecules through well characterized mechanisms of action. Our exosome platform, has advanced through internal research and external collaborations, including with the National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID), Johns Hopkins University, the Department of Defense (DoD), U.S. Army Institute of Surgical Research (USAISR), and Cedars-Sinai Medical Center.

Preclinical data from our StealthX™ platform demonstrated rapid development of a recombinant protein based vaccine against SARS-CoV-2. Building on advancements in RNA and protein science, targeting, and scalable manufacturing, the platform has potential applications across infectious diseases, monogenic disorders, and other indications.

In 2024, Capricor was selected to participate in Project NextGen, an initiative led by the U.S. Department of Health and Human Services aimed at advancing next generation COVID-19 vaccines with broader and longer lasting protection. Under this program, NIAID is sponsoring a Phase 1 clinical trial of our StealthX™ vaccine. The trial will be conducted and overseen by NIAID's Division of Microbiology and Infectious Diseases (DMID), with Capricor supplying the clinical material.

Following the clearance of the Investigational New Drug (IND) application by the FDA, the Phase 1 study initiated in August 2025. The trial includes several dosing arms initially focused on the spike (S) protein, with an additional planned arm which will utilize the nucleocapsid (N) protein, pending separate FDA clearance. If the vaccine meets NIAID's criteria for safety and efficacy, the program may advance to a funded Phase 2 study.

As we advance our exosome platform, our strategy is to identify partners who can provide capital and development expertise to support clinical advancement across targeted indications.

Financial Operations Overview

As of June 30, 2025, we had cash, cash equivalents, and marketable securities totaling approximately $122.8 million. In the fourth quarter of 2024, we submitted our BLA to the FDA, which triggered our second milestone pursuant to the terms of our U.S. Distribution Agreement with Nippon Shinyaku. In January 2025, we received the $10.0 million milestone payment.

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 $25.9 million and approximately $11.0 million, for the three months ended June 30, 2025 and 2024, respectively. Our net losses were approximately $50.3 million and approximately $20.8 million, for the six months ended June 30, 2025 and 2024, respectively. As of June 30, 2025, we had an accumulated deficit of approximately $250.1 million. We expect to incur significant expenses and operating losses for the foreseeable future.

As we seek to develop and commercialize deramiocel 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 deramiocel or our other product candidates.

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 deramiocel and our exosome technologies. As we proceed with the clinical development of deramiocel, 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 U.S. and in other territories across the world, subject to the rights of Nippon Shinyaku.

Our results have included non-cash compensation expense due to the issuance of stock awards and warrants, as applicable. We expense the fair value of stock awards 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 stock 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 June 30, 2025 and 2024 was $0 and approximately $4.0 million, respectively. Clinical Development income for the six months ended June 30, 2025 and 2024 was approximately $0 and $8.9 million. As of June 30, 2025, the Company has fully recognized $50.0 million in development milestone payments received from Nippon Shinyaku related to the Exclusive Commercialization and Distribution Agreement (the “U.S. Distribution Agreement”). The upfront payment of $30.0 million and the first milestone payment of $10.0 million was ratably recognized as revenue using a proportional performance method in relation to the completion of the HOPE-3 clinical trial (Cohort A) whereas the $10.0 million related to the second milestone payment was recognized as revenue at the point in time when the BLA was submitted in December 2024.

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 June 30,			
	2025	2024	Change ($)	Change (%)
Compensation and other personnel expenses	$ 7,510,545	$ 3,596,825	$ 3,913,720	109 %
Duchenne muscular dystrophy program (deramiocel)	9,838,927	5,965,495	3,873,432	65 %
Exosomes platform research	1,164,133	1,011,263	152,870	15 %
Facility expenses	1,215,472	742,964	472,508	64 %
Stock-based compensation	1,930,467	852,472	1,077,995	126 %
Depreciation and amortization	233,491	200,135	33,356	17 %
Research and other	154,219	135,615	18,604	14 %
Total research and development expenses	$ 22,047,254	$ 12,504,769	$ 9,542,485	76 %

R&D expenses for the three months ended June 30, 2025 increased by approximately $9.5 million, or 76%, compared to the three months ended June 30, 2024. The increase was primarily driven by the following:

- $3.9 million increase in compensation and other personnel expenses primarily due to increases in headcount;
- $3.9 million increase in DMD (deramiocel) program-related expenses primarily related to our HOPE-3 clinical trial, our HOPE-2 OLE clinical trial and expanded manufacturing production efforts for deramiocel in preparation for potential commercial launch;
- $0.2 million increase in research expenses related to our exosomes platform, primarily related to our collaboration with NIAID;
- $0.5 million increase in facility expenses primarily related to expanded leased space; and
- $1.1 million increase in stock-based compensation expense primarily due to increases in headcount.

	Six months ended June 30,			
	2025	2024	Change ($)	Change (%)
Compensation and other personnel expenses	$ 12,920,970	$ 7,013,414	$ 5,907,556	84 %
Duchenne muscular dystrophy program (deramiocel)	17,544,121	11,244,139	6,299,982	56 %
Exosomes platform research	2,685,067	1,675,101	1,009,966	60 %
Facility expenses	2,300,893	1,227,513	1,073,380	87 %
Stock-based compensation	4,669,051	1,840,199	2,828,852	154 %
Depreciation and amortization	448,455	379,303	69,152	18 %
Research and other	394,269	226,113	168,156	74 %
Total research and development expenses	$ 40,962,826	$ 23,605,782	$ 17,357,044	74 %

R&D expenses for the six months ended June 30, 2025 increased by approximately $17.4 million, or 74%, compared to the six months ended June 30, 2024. The increase was primarily driven by the following:

- $5.9 million increase in compensation and other personnel expenses primarily due to increases in headcount;
- $6.3 million increase in DMD (deramiocel) program-related expenses primarily related to our HOPE-3 clinical trial, our HOPE-2 OLE clinical trial and expanded manufacturing production efforts for deramiocel in preparation for potential commercial launch;
- $1.0 million increase in research expenses related to our exosomes platform, primarily related to our collaboration with NIAID;

- $1.1 million increase in facility expenses primarily related to expanded leased space; and
- $2.8 million increase in stock-based compensation expense primarily due to increases in headcount.

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 June 30,			
	2025	2024	Change ($)	Change (%)
Stock-based compensation	$ 1,716,687	$ 1,300,321	$ 416,366	32 %
Compensation and other personnel expenses	2,139,615	837,474	1,302,141	155 %
Professional services	440,925	360,174	80,751	22 %
Facility expenses	77,970	74,756	3,214	4 %
Depreciation and amortization	252,788	156,800	95,988	61 %
Other corporate expenses	1,043,895	328,363	715,532	218 %
Total general and administrative expenses	$ 5,671,880	$ 3,057,888	$ 2,613,992	85 %

G&A expenses for the three months ended June 30, 2025 increased by approximately $2.6 million, or 85%, compared to the three months ended June 30, 2024. The increase was primarily driven by the following:

- $0.4 million increase in stock-based compensation expense primarily due to increases in headcount;
- $1.3 million increase in compensation and other personnel expenses related to increases in headcount and recruiting costs; and
- $0.7 million increase in other corporate expenses primarily related to increased overhead costs, related to travel and corporate expenses due to increased headcount.

	Six months ended June 30,			
	2025	2024	Change ($)	Change (%)
Stock-based compensation	$ 4,717,501	$ 3,578,006	$ 1,139,495	32 %
Compensation and other personnel expenses	3,640,458	1,615,407	2,025,051	125 %
Professional services	776,834	784,169	(7,335)	(1)%
Facility expenses	155,289	151,134	4,155	3 %
Depreciation and amortization	443,273	309,039	134,234	43 %
Other corporate expenses	2,005,901	691,899	1,314,002	190 %
Total general and administrative expenses	$ 11,739,256	$ 7,129,654	$ 4,609,602	65 %

G&A expenses for the six months ended June 30, 2025 increased by approximately $4.6 million, or 65%, compared to the six months ended June 30, 2024. The increase was primarily driven by the following:

- $1.1 million increase in stock-based compensation expense primarily due to increases in headcount;
- $2.0 million increase in compensation and other personnel expenses related to increases in headcount and recruiting costs;
- $0.1 million increase in depreciation and amortization expense related to fixed asset purchases and leasehold improvements; and
- $1.3 million increase in other corporate expenses primarily related to increased overhead costs, related to travel and corporate expenses due to increased headcount.

Other Income

Investment Income. Investment income for the three months ended June 30, 2025 and 2024 was approximately $1.8 million and $0.6 million, respectively. Investment income for the six months ended June 30, 2025 and 2024 was approximately $2.5 million and $1.1 million, respectively. The increase in investment income for the three and six months ended June 30, 2025 as compared to the three and six months ended June 30, 2024 is due to a higher principal balance in our marketable securities, savings and money market fund accounts.

Products Under Active Development

Deramiocel for the treatment of DMD – The expenses for our DMD program include costs for personnel, clinical, regulatory and manufacturing-related expenses, including expenses related to the scale-up for potential commercial scale manufacturing if our deramiocel product is approved. In 2025, we expect to spend approximately $45.0 million to $50.0 million primarily consisting of CMC expansion, product inventory buildout, clinical, regulatory and pre-commercial expenses for our deramiocel program.

Exosome-Based Therapeutics and Vaccines – Our exosome platform is in early-stage preclinical development. We expect to spend approximately $5.0 million to $7.0 million during 2025 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 deramiocel 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; and
- the costs, requirements and timing of, and the ability to secure, regulatory approvals;

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of June 30, 2025 and December 31, 2024 and our net increase (decrease) in cash, cash equivalents, and marketable securities for the six months ended June 30, 2025 and 2024 and is intended to supplement the more detailed discussion that follows. The amounts stated in the tables below are expressed in thousands. We estimate our current cash, cash equivalents, and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2026.

Liquidity and capital resources	June 30, 2025	December 31, 2024
Cash and cash equivalents	$ 23,241	$ 11,287
Marketable securities	$ 99,559	$ 140,229
Working capital	$ 95,729	$ 142,359
Stockholders' equity	$ 104,977	$ 145,462

Cash flow data	Six months ended June 30, 2025	2024
Cash provided by (used in):		
Operating activities	$ (26,556)	$ (13,557)
Investing activities	38,440	5,193
Financing activities	70	4,358
Net increase (decrease) in cash and cash equivalents	$ 11,954	$ (4,006)

Our total cash, cash equivalents and marketable securities as of June 30, 2025 were approximately $122.8 million compared to approximately $151.5 million as of December 31, 2024. The decrease in cash, cash equivalents and marketable securities from December 31, 2024 to June 30, 2025 is primarily due to our continuing efforts in preparing the Company for potential commercialization. As of June 30, 2025, we had approximately $28.6 million in total liabilities, of which approximately $12.0 million relates to deferred revenue, and approximately $95.7 million in net working capital.

Cash used in operating activities was approximately $26.6 million and approximately $13.6 million for the six months ended June 30, 2025 and 2024, respectively. The increase of approximately $13.0 million in cash used in operating activities is due to an approximately $29.5 million increase in net loss for the six months ended June 30, 2025 as compared to the same period in 2024. Furthermore, there was an increase of approximately $3.7 million in stock-based compensation, approximately $8.9 million in deferred revenue, and approximately $2.9 million in accounts payable and accrued expenses for the six months ended June 30, 2025 as compared to the same period in 2024. 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 provided by investing activities of approximately $38.4 million for the six months ended June 30, 2025 and cash flow used in investing activities of approximately $5.2 million for the six months ended June 30, 2024, respectively. The change in investing activities for the six months ended June 30, 2025 as compared to the same period of 2024 is due to the net effect from purchases, sales and maturities of marketable securities and the purchase of approximately $2.6 million in property and equipment, leasehold improvements and construction in progress.

We had cash flow provided by financing activities of $69,934 and approximately $4.4 million for the six months ended June 30, 2025 and 2024, respectively. The decrease in cash provided by financing activities for the six months ended June 30, 2025 as compared to the six months ended June 30, 2024 is primarily due to the net proceeds from the sale of common stock during 2024.

From inception through June 30, 2025, we financed our operations primarily through private and public sales of our equity securities, 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 obtaining marketing approval both in the United States and in countries outside of the United States.

Collaborations

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 will be responsible for the clinical development and manufacturing of deramiocel. Nippon Shinyaku and NS Pharma, Inc. (its wholly-owned U.S. subsidiary) will be responsible for the distribution of deramiocel in the United States. Pursuant to the U.S Distribution Agreement, Capricor received an upfront payment of $30.0 million in 2022. The first milestone payment of $10.0 million was paid upon completion of the futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. The second milestone payment of $10.0 million was triggered in December 2024 upon submission of the BLA to the FDA seeking marketing approval of deramiocel in the United States. Additionally, there is another potential milestone of $80.0 million due to Capricor upon receipt of marketing approval. The foregoing milestones are considered development milestones under the terms of the U.S. Distribution Agreement. Further, there are various potential sales-based milestones, if commercialized, tied to the achievement of certain sales thresholds for annual net sales of deramiocel of up to $605.0 million. Subject to regulatory approval, Capricor will have the right to receive a share of product revenue which falls between 30 and 50 percent.

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 deramiocel 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 deramiocel in Japan. Capricor will be responsible for the conduct of clinical development and regulatory approval in Japan, as may be required, as well as the manufacturing of deramiocel. Subject to regulatory approval, Capricor or its designee will hold the Marketing Authorization in Japan if the product is approved in that territory.

Binding Term Sheet with Nippon Shinyaku (Territory: Europe)

On September 16, 2024, Capricor entered into a Binding Term Sheet (the "Term Sheet") with Nippon Shinyaku for the commercialization and distribution of deramiocel for the treatment of DMD in the European region, as defined in the Term Sheet. Subject to finalization of a definitive agreement, under the terms of the Term Sheet, Capricor would be responsible for the development and manufacturing of deramiocel for potential approval in the European region. Nippon Shinyaku would be responsible for the sales and distribution of deramiocel in the European region. Subject to regulatory approval, Capricor would receive a double-digit share of product revenue and additional development and sales-based milestone payments. If the definitive agreement is entered into on the same economic terms as the term sheet, Capricor will receive an upfront payment of $20.0 million upon execution of the definitive agreement, with potential additional development and sales-based milestone payments of up to $715.0 million. At this time, Capricor and Nippon Shinyaku have entered into several amendments to the Term Sheet, pursuant to which the parties agreed to extend the date during which the parties shall negotiate the definitive agreement to September 30, 2025.

Financing Activities by the Company

October 2024 Underwritten Public Offering

On October 16, 2024, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Piper Sandler and Oppenheimer as representatives of the underwriters (the "Underwriters"), pursuant to which the Company agreed to sell and issue, in a public offering, an aggregate of 5,073,800 shares of common stock, including the exercise in full of the underwriters' option to purchase additional shares to cover over allotments, at a public offering price of $17.00 per share for total gross proceeds of approximately $86.3 million, before deducting underwriting commissions and other offering expenses payable by the Company. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to the Underwriters, as well as legal and accounting fees in the aggregate amount of approximately $5.4 million.

September 2024 Private Placement

On September 16, 2024, the Company entered into a Subscription Agreement with Nippon Shinyaku pursuant to which the Company agreed to issue and sell to Nippon Shinyaku in a private placement (the "Private Placement"), an aggregate of 2,798,507 shares of the common stock of the Company at a price per Share of $5.36, which was issued at a 20% premium to the 60-day volume-weighted average price, for an aggregate purchase price of approximately $15.0 million. The Subscription Agreement also includes lock-up provisions restricting Nippon Shinyaku from selling or otherwise disposing of shares of the Company's common stock until the six-month anniversary of the Closing Date.

In connection with the Private Placement, the Company also entered into a Registration Rights Agreement with Nippon Shinyaku on September 16, 2024 (the "Registration Rights Agreement"). Pursuant to the terms of the Registration Rights Agreement, the Company has filed with the SEC a registration statement to register for resale the shares sold in the Private Placement, which registration statement was declared effective on November 8, 2024.

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 the Company issued and sold shares of our common stock through Wainwright as sales agent. The Sales Agreement provided that Wainwright would 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 October 1, 2024, the Company sold an aggregate of 9,228,383 shares of common stock under the ATM Program at an average price of approximately $8.13 per share for gross proceeds of approximately $75.0 million which represents all amounts that were available to be sold. Effective October 1, 2024, the ATM Program was closed and terminated. 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 $2.4 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 I/II HOPE-Duchenne clinical trial investigating deramiocel 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 potentially 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 could have been required to pay to CIRM was 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 had 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. In 2019, Capricor completed all milestones and close-out activities associated with the CIRM Award and expended all funds received.

The Company accounts for this award as a liability rather than income. As of June 30, 2025, Capricor's principal liability balance for the CIRM Award was approximately $3.4 million, excluding any accrued interest.

On February 26, 2025, Capricor notified CIRM of its election to convert the CIRM Award into a loan. As a result, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements. The terms of the loan agreement are currently under discussion with CIRM. Depending on the results of these discussions, accrued interest on the CIRM Award could reach up to approximately $7.1 million and may continue to accrue over time until the final payout. There was no accrued interest recorded as of June 30, 2025.

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

Accounting Standards Codification ("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 Accounting Standards Update ("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 two types: development 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.

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, manufacturing and commercial activities, 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 ongoing 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 options and restricted stock awards, as applicable. We have issued stock options and restricted stock awards 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 stock options and restricted stock awards under the 2020 Plan, the 2021 Plan, and the 2025 Plan, and no longer issues stock awards 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. For stock options, when more precise pricing data is unavailable, we determine the fair value 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. For restricted stock awards, we determine the fair value using the Company’s stock price at the grant date.

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 November 2024, the FASB issued ASU No. 2024-03, Disaggregation of Income Statement Expenses (Subtopic 220-40). The ASU requires the disaggregated disclosure of specific expense categories, including purchases of inventory, employee compensation, depreciation, and amortization, within relevant income statement captions. This ASU also requires disclosure of the total amount of selling expenses along with the definition of selling expenses. The ASU is effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Adoption of this ASU can either be applied prospectively to consolidated financial statements issued for reporting periods after the effective date of this ASU or retrospectively to any or all prior periods presented in the consolidated financial statements. Early adoption is also permitted. This ASU will likely result in the required additional disclosures being included in our consolidated financial statements, once adopted. 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 June 30, 2025, the fair value of our cash, cash equivalents and marketable securities was approximately $122.8 million. Additionally, as of June 30, 2025, Capricor's investment portfolio was classified as cash, cash equivalents and marketable securities, which consisted primarily of money market funds and bank money market accounts, 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 materially 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 June 30, 2025 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.

On July 17, 2025 a putative securities class action was filed in the Southern District of California, naming Capricor Therapeutics, Inc. and our chief executive officer, Linda Marbán. The action alleges certain violations of the U.S. federal securities laws and seeks unspecified damages.

On August 1, 2025 a derivative action was filed in the Southern District of California naming each of the Directors on the Board of Capricor Therapeutics, Inc. The action alleges, among other things, breaches of fiduciary duties and seeks unspecified damages.

Item 1A. Risk Factors.

Part 1, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the SEC on March 26, 2025, 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.

We will incur costs in connection with defending securities class action litigation and derivative claims recently initiated by certain of our stockholders.

As noted in our Form 10-K for the year ended December 31, 2024, we may become subject to securities class action litigation or litigation initiated by individual stockholders. This risk is especially relevant due to our dependence on positive clinical trial outcomes and regulatory approvals. As noted in this Form 10-Q, we have now received notice of a putative class action and of a derivative action from certain of our stockholders. Responding to these claims will be costly and time-consuming to us, and may cause management to have to divert attention and resources from the pursuit of our business strategies, any of which could harm our business and result in a decline in the market price of our common stock.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Arrangements

During the three months ended June 30, 2025, none of the directors or executive officers of the Company adopted or terminated any contracts, instructions, or written plans for the purchase or sale of the Company's securities that were intended to meet the affirmative defense conditions of Rule 10b5-1(c) or any other "non-Rule 10b5-1 trading arrangement".

Item 6. Exhibits.

3.1	Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the 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	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 May 15, 2024).
3.5	Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 9, 2007).
3.6	Certificate of Amendment of the 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).
10.1	Capricor Therapeutics, Inc. 2025 Equity Incentive Plan (incorporated by reference to Exhibit 4.7 to the Company's Current Report on Form S-8, filed with the SEC on June 16, 2025).
10.2	Form of Stock Option Agreement for Capricor Therapeutics, Inc. 2025 Equity Incentive Plan (incorporated by reference to Exhibit 4.8 to the Company's Current Report on Form S-8, filed with the SEC on June 16, 2025).
10.3	Consulting Agreement between Capricor, Inc. and Earl Collier, Jr., dated May 22, 2025.* +
31.1	Certification of Principal Executive Officer.*
31.2	Certification of Principal Financial Officer.*
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101	The following financial information from Capricor Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2025 formatted in Inline eXtensible Business Reporting Language (iXBRL): (i) Condensed Consolidated Balance Sheets as of June 30, 2025 and December 31, 2024, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity, (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.
+ Portions of the exhibit have been excluded because it is both not material and is the type of information that the registrant treats as private or confidential.

SIGNATURES

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

CAPRICOR THERAPEUTICS, INC.

Date: August 11, 2025	By: /s/ Linda Marbán, Ph.D. Linda Marbán, Ph.D. Chief Executive Officer *(Principal Executive Officer)*
Date: August 11, 2025	By: /s/ Anthony J. Bergmann Anthony J. Bergmann Chief Financial Officer *(Principal Financial and Principal Accounting Officer)*

***Portions of the exhibit have been excluded because it is both not material and is the type of information that the registrant treats as private or confidential.**

CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT ("**Agreement**") is entered into as of the 22nd day of May, 2025 (the "**Effective Date**"), by and between **Capricor Therapeutics, Inc.** a Delaware corporation ("Capricor"), whose offices are located at 10865 Road to the Cure, Ste. 150, San Diego, California 92121 and **Earl Collier, Jr.**, an individual whose address is [***] ("**Consultant**").

RECITALS

A. Capricor and its subsidiary, Capricor, Inc., are engaged in the development of products designed to treat disease (all such present and future businesses being engaged in by Capricor and its subsidiary being referred to herein as the "**Business**"), with shares quoted on the NASDAQ exchange under the symbol CAPR.

B. Consultant has been serving as a director on Capricor's Board of Directors since 2011 and has elected to resign his directorship with Capricor.

C. Capricor desires to engage Consultant from time to time to utilize his knowledge as an independent contractor to perform certain services related to strategic consulting, and Consultant desires to accept such engagement on the terms and conditions specified herein.

NOW, THEREFORE, in consideration of the mutual promises contained herein and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereby agree as follows:

1. Engagement of Consultant.

1.1 Subject to the terms and conditions of this Agreement, Capricor hereby engages Consultant to provide strategic consulting services for Capricor from time to time (the "**Services**").

1.2 Consultant agrees to perform the Services in a timely, professional, and workmanlike manner. In connection with such engagement, Consultant shall provide advice, guidance and assistance with respect to corporate strategies as may be requested by the Company from time to time. In performing the Services, Consultant will comply with all laws, rules, regulations, professional standards, business conduct, and regulatory guidelines that may be applicable to Consultant, Capricor, and/or the Services to be provided hereunder, including, without limitation, SEC and other government laws and regulations.

2. Services Non-Exclusive. During the continuance of this Agreement, it shall not be a violation of this Agreement for Consultant to engage in other ventures or activities, whether existing now or in the future, including, but not limited to, rendering services of a business, commercial, or professional nature to any other person or organization, whether for compensation or otherwise so long as such activities do not interfere with the Services to be performed by Consultant hereunder. If Consultant is engaged or desires to engage in other ventures or activities involving the same or similar products being developed by Capricor, Consultant shall disclose in writing to Capricor the general nature and scope of such other business ventures or activities, without disclosing any confidential information of any third party. Capricor may terminate this Agreement if Capricor believes that Consultant's participation in such venture or activity would pose an actual or potential conflict of interest or would be materially detrimental to the business interests of Capricor.

3. Remuneration.

3.1 Consulting Fee. As compensation for any Services requested by Capricor to be performed by Consultant, Capricor will pay Consultant a fee at the rate of $200.00 per hour worked. Consultant understands and agrees that no Services will be performed unless specifically requested by Capricor.

3.2 Invoices. Within ten (10) days following the end of each calendar month during the continuance of this Agreement, Consultant shall submit to Capricor an invoice describing the Services performed and expenses incurred, if any, during the preceding calendar month and payment shall be due within thirty (30) days after receipt of an invoice.

3.3 Vesting of Stock Options. The parties acknowledge that Consultant was previously granted various stock options by Capricor. The parties agree that the transition from a director to a consultant of Capricor shall not effect a "Termination of Service Provider" as such term is defined under the terms of the Equity Incentive Plans of Capricor Therapeutics, Inc., (the "**Plans**") under which Plans Consultant's stock options were granted. The parties further acknowledge and agree that Consultant shall be entitled to continue vesting any unvested options existing as of the Effective Date, and that Consultant shall have the ability to exercise his vested options pursuant to the terms of the Stock Option Agreements entered into between the parties under the Plans until that date which is ninety (90) days after the termination date of this Agreement,

3.4 **Taxes.** Consultant shall be solely responsible for the payment of all taxes and contributions imposed or required by the tax laws of any jurisdiction that pertain to the compensation amounts paid to Consultant under this Agreement. Consultant shall complete and provide to Capricor Internal Revenue Form W-9 and Capricor shall issue a Form 1099 to Consultant in respect of the payments made hereunder.

4. **Independent Contractor Status.** Consultant shall at all times serve as an independent contractor when acting under this Agreement. No provision of this Agreement shall be interpreted to conflict with the intent of the parties that Consultant's legal status with respect to this Agreement and the Services being provided hereunder shall at all times be that of an independent contractor, and not as an employee, partner, or joint venturer of Capricor. Consultant acknowledges and agrees that he shall not have the power or right to bind or obligate Capricor, nor shall he hold himself out as having such authority. Consultant further agrees that in connection with his engagement as a Consultant, he will not be entitled or eligible to receive any benefits of any kind such as insurance benefits, workers compensation coverage, social security, unemployment insurance, or otherwise. Capricor shall not withhold on behalf of Consultant any sums for federal, state or local income taxes, unemployment insurance, social security, or any other withholding of any kind pursuant to any law. Consultant further agrees to indemnify and hold Capricor harmless from and against liability for such taxes, including deficiencies, assessments, interest and penalties for the nonpayment of such taxes and/or contributions.

5. **Confidentiality.**

5.1 In the course of providing Services to Capricor, Consultant may acquire access to Capricor's Confidential Information. For purposes hereof, "**Confidential Information**" means confidential, trade secret, and/or proprietary information of Capricor and its affiliates, whether in written, printed, verbal or electronic form, including, without limitation: (a) research and development activities, pre-clinical and clinical trial information and data, product design details and specifications, processes, formulations, techniques, methodologies, patent strategies, technology and know-how, sales and marketing plans, finances and business forecasts, procurement requirements, vendor information, customer lists, personnel information, and strategic plans; (b) other information that Capricor identifies in writing as confidential to Consultant; (c) information that Consultant knows or has reason to know is confidential, trade secret, or proprietary information of Capricor; and (d) information which is of such a nature or the manner or circumstance in which such information is disclosed is such that it may be reasonably inferred to be confidential and/or proprietary to Capricor.

5.2 **Exclusions**. Confidential Information will not include information that: (a) is now, or hereafter becomes generally known or available to the public through no act or failure to act on the part of Consultant; (b) was acquired by Consultant before receiving such information from Capricor through no breach of any duty of confidentiality owed to Capricor and without restriction as to use or disclosure; (c) is hereafter rightfully furnished to Consultant by a third party without any breach of any duty of confidentiality owed to Capricor and without restriction as to use or disclosure; or (d) is information that Consultant can document was independently developed by Consultant without any use of Capricor's Confidential Information.

5.3 Consultant agrees: (a) to hold Capricor's Confidential Information in strict confidence and not to disclose the Confidential Information to any other person or entity without the prior written consent of Capricor; (b) not to use, at any time following the execution of this Agreement, any Confidential Information for his own benefit or for the benefit of any other person or entity for any purpose other than in performing the Services required hereunder and then, only to the extent and for such purposes authorized by Capricor. Consultant shall be responsible for any unauthorized use or disclosure of Capricor's Confidential Information by Consultant.

5.4 Consultant acknowledges and agrees that all of Capricor's Confidential Information is owned solely by Capricor (or its licensors or affiliates) and that nothing contained in this Agreement will be construed as granting any rights to Consultant, by license or otherwise, to any of Capricor's Confidential Information, all of which rights are specifically reserved by Capricor. Consultant further agrees not to copy all or any part of the Confidential Information or any documentation related thereto except as may be necessary for him to provide the Services and further, not to modify, adapt, translate, reverse engineer, decompile, disassemble, or otherwise attempt to discover any additional information with respect to the Confidential Information. Capricor and its assigns shall be the sole owner of all patents and other intellectual property rights in connection with Capricor's Confidential Information. Consultant hereby assigns to Capricor any rights Consultant may have or may acquire in such Confidential Information.

5.5 Consultant recognizes that Capricor has received and in the future will receive from third parties their confidential or proprietary information subject to a duty on Capricor's part to maintain the confidentiality of such information and, in some cases, to use it only for certain limited purposes. Consultant agrees that he owes Capricor and such third parties, both during the term of this Agreement and thereafter, a duty to hold all such confidential or proprietary information in the strictest confidence and not to disclose it to any person, firm or corporation (except in a manner that is consistent with Capricor's agreement with such third party) or use it for the benefit of any person or entity other than Capricor or such third party (consistent with Capricor's agreement with such third party).

5.6 Consultant shall not make available to Capricor any information concerning non- Capricor confidential research activities carried out by any third party or any other entity, or the results thereof, or intellectual property arising therefrom, except for information, results, or property available generally to the scientific community at large through published reports or otherwise.

5.7 Consultant agrees that his obligations hereunder are necessary and reasonable to protect Capricor's business interests and that the unauthorized disclosure or use of Capricor's Confidential Information would cause irreparable harm and significant injury, the degree of which may be difficult to ascertain. Consultant further acknowledges and agrees that in the event of any actual or threatened breach of this Agreement, Capricor may have no adequate remedy at law and accordingly, that Capricor will have the right to seek an immediate injunction enjoining any breach or threatened breach of this Agreement, without the necessity of proving actual damages, as well as the right to pursue any and all other rights and remedies available at law or in equity for such breach or threatened breach.

5.8 This Agreement shall apply to any Confidential Information disclosed to Consultant after the Effective Date and to Confidential Information disclosed earlier to the extent Consultant began rendering Services to Capricor prior to the Effective Date. The obligations of Consultant under this Article 5 as to the Confidential Information he has received hereunder shall continue in full force and effect regardless of any attempted or actual termination or expiration of this Agreement.

5.9 Upon the termination of this Agreement or earlier request by Capricor, Consultant will deliver to Capricor (and will not keep in Consultant's possession, recreate or deliver to anyone else) any and all devices, records, data, notes, reports, proposals, lists, correspondence, specifications, drawings, blueprints, sketches, materials, equipment, computer disks other documents, materials or property, together with all copies thereof (in whatever medium recorded) belonging to Capricor, its affiliates, licensors, successors or assigns.

5.10 Unless the prior written consent of Capricor has been obtained, Consultant shall not discuss or mention in scientific publications, medical literature, abstracts or verbal presentations any information regarding Capricor, including, without limitation, any information related to Capricor's business, products, processes, data, plans, strategies or Confidential Information, unless such information is in the public domain not by reason of a breach of any confidentiality obligation owed to Capricor.

5.11 In the event Consultant is required to disclose Confidential Information of Capricor by any applicable law, regulation, legal process, judicial order or by any applicable order or requirement of any governmental or regulatory authority, he may do so only to the extent required; provided, however, Consultant shall (a) first give prompt notice to Capricor of the required disclosure sufficiently in advance of making the required disclosure to allow Capricor a reasonable opportunity to take steps to object to, prevent, and/or limit its disclosure or obtain a protective or other similar order with respect to the required disclosure (collectively “Protective Measures”); (b) if requested by Capricor, cooperate with Capricor in seeking such Protective Measures; and (c) restrict disclosure to only that portion of the Confidential required to be disclosed. Confidential Information disclosed pursuant to this Section 5.11 shall not lose its confidential treatment for all other purposes.

6. Property Rights of the Parties.

6.1 **Generally**. Consultant hereby acknowledges and agrees that any and all useful art, discoveries, improvements, modifications, designs, contributions, processes, data, techniques, know- how, methods, trade secrets, intellectual property, or ideas (whether patentable or not) developed by him, either alone or in conjunction with others, relating to the Services provided hereunder (each an “Invention”) shall immediately become and shall remain the sole property of Capricor and its assigns, as works made for hire or otherwise. Consultant shall not have any publication rights, and all of the same shall belong exclusively to Capricor or its assigns, as applicable.

6.2 **Disclosure and Assignment.** Consultant shall promptly disclose to Capricor each such Invention which has been or shall be made, conceived, learned, or reduced to practice or writing by Consultant, either alone or with others in connection with or related to Capricor’s business. Consultant hereby assigns to Capricor and its assigns, all right, title and interest worldwide (including, but not limited to, rights to Inventions, subject matter (whether or not patentable), copyrights and trademarks) he may have or may acquire in the Inventions, and all benefits and/or rights resulting therefrom, without further compensation.

6.3 **Further Assurances.** Both during and after termination of this Agreement, Consultant shall, at the request and cost of Capricor, promptly sign, execute, make and do all such deeds, documents, assignments, acts and things as Capricor or its duly authorized officers may reasonably require: (i) to apply for, obtain, register and vest in the name of Capricor alone (unless Capricor otherwise directs) patents, copyrights, trademarks or other analogous protection in any country throughout the world relating to such Inventions, and when so obtained or vested to renew and restore the same; and (ii) to assist in the defense of any judicial, opposition or other proceedings in respect of such applications and any judicial, opposition or other proceeding, petition or application for revocation of any such patent, copyright, trademark or other analogous protection. If Capricor is unable, after reasonable effort, to secure the signature of Consultant, as required by this paragraph on any application for patent, copyright, trademark or other analogous registration or other documents regarding any legal protection relating to an Invention that is assigned to Capricor or its assignees hereunder, whether because of the physical or mental incapacity of Consultant, or for any other reason whatsoever, Consultant hereby irrevocably designates and appoints Capricor and its duly authorized officers and agents as his agent and attorney-in-fact, to act for and on his behalf and stead to execute and file any such application or applications or other documents and to do all other lawfully permitted acts to further the prosecution and issuance of patent, copyright or trademark registrations or any other legal protection thereon with the same legal force and effect as if executed by him.

6.4 **No License Intended.** Nothing contained in this Agreement nor the disclosure of any Confidential Information to Consultant shall be deemed to grant Consultant any right or license under any patents or patent applications or to any know-how, technology, invention, trademark, copyright or any other intellectual property disclosed by Capricor or otherwise learned by Consultant, and such intellectual property shall remain the sole and exclusive property of Capricor.

7. **Compliance with Business Ethics and Laws.**

7.1 **Ethical Conduct.** It is the policy of Capricor to conduct its business at all times in accordance with the highest standards of corporate, medical and business ethics as set forth in Capricor's Code of Ethics as posted on its website. Consultant agrees to comply with those standards in all matters relating to the performance of the Services under this Agreement.

7.2 **Compliance with Laws.** Consultant shall comply with all applicable laws affecting this Agreement and his performance hereunder. Upon written notice from Capricor, Consultant shall provide such information as Capricor shall reasonably consider necessary to verify compliance by Consultant with the provisions of this Section 7.2.

7.3 **Anti-Bribery and Anti-Corruption.**

(a) Consultant confirms that he has not been given or promised, and will not accept, any payment or anything of value, directly or indirectly, except for the compensation specifically set forth in this Agreement as payment for the Services. Consultant shall, in his performance under this Agreement, take all actions necessary and appropriate to assure that he complies with all applicable international, federal, state, and local laws and regulations, including, without limitation, the Anti-Kickback Statute (42 U.S.C. SS 1320a-7b (b)), the Public Contracts Anti-Kickback Act (41 U.S.C. SS 51 et seq.) and the Stark Law (42 U.S.C. 1395nn) and the Foreign Corrupt Practices Act (FCPA).

(b) Consultant agrees that he will not, on Capricor's behalf, make any payment or make any donation, or give anything of value, either directly or indirectly, to an official of any government for the purpose of influencing an act of decision of the official in his or her official capacity or inducing the official to use his or her influence to assist Capricor in obtaining or maintaining business or for any other purpose prohibited by law or the public policies of any country or state.

(c) Neither Consultant nor any related person shall, in the name, on behalf or for the benefit of Capricor or any of its affiliates or in respect of Capricor's products or activities, offer, pay, give, promise to pay or give, or authorize the payment or gift of money or anything of value to any official, political party (or employee of a customer) or to any other person at the request, suggestion or direction of any official, political party (or employee of a customer) or when all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to any such person for the purpose of obtaining or retaining business or favorable governmental action.

8. **Insider Trading.** Capricor is a public company that is subject to the reporting requirements of the Securities and Exchange Act of 1934, as amended, and as such, in the course of her duties hereunder, Consultant may receive from Capricor or others information that may be considered material, nonpublic information concerning. Accordingly, Consultant agrees NOT to:

(a) buy or sell any security, option, bond or warrant while in possession of relevant material, nonpublic information received from Capricor or others in connection herewith; or

(b) provide any person with material, nonpublic information, received from Capricor, including any relative, associate, or other individual who intends to, or may, (i) trade securities with respect to Capricor which is the subject of such information, or (ii) otherwise directly or indirectly benefit from such information.

9. **Term and Termination.**

9.1 **Term.** This Agreement shall commence as of the Effective Date and shall continue in effect until terminated by one of the parties in accordance with the terms of this Article 9.

9.2 **Termination**. Notwithstanding the provisions of Section 9.1, the following shall apply:

(a) This Agreement shall immediately terminate without further action by Capricor in the event of Consultant's death;

(b) This Agreement may be terminated by either party upon fourteen (14) days' prior written notice if the other party commits a material breach of this Agreement and such breach is not cured within such fourteen (14) day period;

(c) Either party shall have the right to terminate this Agreement without cause upon at least thirty (30) days' written notice to the other party; and

(d) Capricor may terminate this Agreement upon written notice to Consultant upon the occurrence of any of the following:

(1) The commission of an act of fraud or dishonesty by Consultant;

(2) The unauthorized use or disclosure of Confidential Information by Consultant;

(3) The failure by Consultant to perform the Services at a level of quality acceptable to Capricor; or

(4) Any conduct by Consultant that is in violation of applicable law or that is injurious to Capricor or its business reputation.

9.3 In the event of a termination of this Agreement, Capricor shall not have any obligation to Consultant for fees, compensation or for damages of any kind, except for accrued and unpaid compensation through the effective date of such termination. Any documents or information in the possession of Consultant shall be immediately returned to Capricor upon termination.

10. Miscellaneous.

10.1 Entire Agreement. This Agreement contains the entire understanding between the parties hereto and supersedes any prior understandings and/or written or oral agreements between them respecting all subject matters contained within this Agreement. There are no representations, agreements, arrangements or undertakings, oral or written, between and among the parties hereto relating to the subject matter of this Agreement which are not fully expressed herein.

10.2 Severability. In the event that any provision of this Agreement may be held to be invalid or unenforceable, the same shall be deemed severable and shall not affect in any respect whatsoever the validity of the remainder of this Agreement.

10.3 Waiver. To the fullest extent permitted by law, no failure or delay by a party to insist upon the strict performance of any term, condition, covenant or agreement of this Agreement or any other agreement referred to herein, or to exercise any right, power or remedy hereunder or there under or consequent upon a breach hereof or thereof, shall constitute a waiver of any such term, condition, covenant, agreement, right, power or remedy or of any such breach, or preclude such party from exercising any such right, power, or remedy at any later time or times.

10.4 Amendments. This Agreement may be amended or altered but such amendment or alteration shall only be effective when reduced in writing and signed by each of the parties hereto or their authorized representatives.

10.5 Counterparts. This Agreement may be executed into any number of counterparts, each of which shall be deemed an original, but all of which shall together constitute one and the same instrument. Facsimile and electronically scanned signatures shall be deemed the same as originals and shall be legally binding.

10.6 Notice. Any notice, offer, demand, request, consent, approval or other instrument which may or is required to be given or made under this Agreement shall be given or be made in writing and shall be served personally, by nationally recognized courier, transmitted by electronic or facsimile transmission, or mailed by prepaid registered post and shall be addressed to the addresses set forth in the introductory paragraph of this Agreement or to such other address provided by a party in writing to the other party. A notice delivered by regular or certified U.S. Mail will be deemed to have been delivered on the third business day after the post-mark, if affixed by the U.S. Postal Service. Any other notice will be deemed to have been received on the date and time of the signed receipt or confirmation of delivery or transmission thereof.

10.7 Assignability. This Agreement is personal between Consultant and Capricor. Consultant shall not assign Consultant's rights or delegate his duties under this Agreement, in whole or in part, without the prior written consent of Capricor, which consent can be withheld at Capricor's sole discretion. Capricor shall have the right to assign its rights and delegate its duties under this Agreement in whole or in part without the consent of Consultant.

10.8 Third Party Rights. No person who is not a party to this Agreement has or shall have any rights to enforce any terms of this Agreement.

10.9 **Survival**. Notwithstanding any other provision of this Agreement to the contrary, the provisions of Sections 1.2, 3.4, 9.3 and Articles 4-8 and 10 (and each of their subsections) shall survive the expiration or termination of this Agreement as necessary to give full effect to all of the provisions contained therein.

IN WITNESS WHEREOF, the parties have executed this Consulting Services Agreement as of the Effective Date first above written.

CAPRICOR THERAPEUTICS, INC.

By:	/s/ Karen Krasney
Name:	Karen Krasney
Title:	EVP and General Counsel

EARL COLLIER, JR.

By:	/s/ Duke Collier
Name:	Due Collier
Title:	Consultant

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Linda Marbán, Ph.D., certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 11, 2025

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

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Anthony J. Bergmann, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 11, 2025

/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 June 30, 2025 (the "**Report**") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: August 11, 2025

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

Exhibit 32.2

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

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

(1) the Quarterly Report on Form 10-Q of the Company for the period ended June 30, 2025 (the "**Report**") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: August 11, 2025

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