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

FORM 10-Q

☒ **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended September 30, 2026**

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 Global Select 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 November 9, 2026, there were 58,142,114 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 (the "Exchange Act"), 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:

- regulatory developments involving products and our facilities, including the results of the review by the U.S. Food and Drug Administration ("FDA") of our lead product candidate, Deramiocel (also referred to as CAP-1002);
- the potential outcome of our dispute with Nippon Shinyaku Co., Ltd ("Nippon Shinyaku") and NS Pharma, Inc. (collectively, "NS") with respect to the distribution of Deramiocel;
- our ability to market and sell any of our products, including our ability to market and sell Deramiocel if we are granted the ability to market and sell Deramiocel ourselves or through distribution channels in the United States other than NS;
- the results of pending securities litigation claims, derivative actions and other claims brought against us by stockholders, former employees and other commercial parties;
- the results of the patent infringement claim brought against us by Mesoblast International Sàrl ("Mesoblast");
- how long we expect to maintain liquidity to fund our planned level of operations and our ability to obtain additional funds for our operations and other financial obligations;
- 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 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 Deramiocel;
- 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 ("BLA"), and other regulatory submissions;
- the impact of any reductions in force or changes in regulatory priorities at the U.S. federal agencies responsible for overseeing our industry;
- 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;
- 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 and under Part II, Item 1A, "Risk Factors" in the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2026 and June 30, 2026 and in this Quarterly Report on Form 10-Q. 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

	September 30, 2026 (unaudited)	December 31, 2025
CURRENT ASSETS		
Cash and cash equivalents	$ 44,279,993	$ 287,847,312
Marketable securities	153,300,986	30,281,603
Prepaid expenses and other current assets	4,671,216	4,810,841
TOTAL CURRENT ASSETS	202,252,195	322,939,756
PROPERTY AND EQUIPMENT, net	37,613,754	18,312,238
OTHER ASSETS		
Lease right-of-use assets, net	87,130,283	13,537,820
Other assets	3,374,189	1,159,480
TOTAL ASSETS	$ 330,370,421	$ 355,949,294
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 3,047,946	$ 1,654,754
Accrued expenses	13,327,905	15,557,646
Lease liabilities, current	1,519,196	202,376
CIRM liability, current	—	6,421,984
Deferred revenue, current	12,000,000	12,000,000
TOTAL CURRENT LIABILITIES	29,895,047	35,836,760
LONG-TERM LIABILITIES		
Lease liabilities, net of current	90,710,765	14,320,389
TOTAL LONG-TERM LIABILITIES	90,710,765	14,320,389
TOTAL LIABILITIES	120,605,812	50,157,149
COMMITMENTS AND CONTINGENCIES (NOTE 15)		
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, 58,138,989 and 57,370,909 shares issued and outstanding, respectively	58,139	57,371
Additional paid-in capital	632,069,948	610,330,105
Accumulated other comprehensive income	(153,893)	283,154
Accumulated deficit	(422,209,585)	(304,878,485)
TOTAL STOCKHOLDERS' EQUITY	209,764,609	305,792,145
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 330,370,421	$ 355,949,294

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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
REVENUE				
Revenue	$ —	$ —	$ —	$ —
TOTAL REVENUE	—	—	—	—
OPERATING EXPENSES				
Research and development	29,558,388	20,359,098	85,801,592	61,321,924
General and administrative	15,124,348	5,924,942	38,599,617	17,662,598
TOTAL OPERATING EXPENSES	44,682,736	26,284,040	124,401,209	78,984,522
LOSS FROM OPERATIONS	(44,682,736)	(26,284,040)	(124,401,209)	(78,984,522)
OTHER INCOME (EXPENSE)				
Other income (loss)	749	(106)	(69,978)	(123,303)
Investment income	2,025,886	1,713,499	7,141,687	4,236,393
TOTAL OTHER INCOME (EXPENSE)	2,026,635	1,713,393	7,071,709	4,113,090
LOSS BEFORE INCOME TAXES	(42,656,101)	(24,570,647)	(117,329,500)	(74,871,432)
(Provision for) benefit from income taxes	—	—	(1,600)	(1,600)
NET LOSS	$ (42,656,101)	$ (24,570,647)	$ (117,331,100)	$ (74,873,032)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	9,648	(543,452)	(437,047)	(182,833)
COMPREHENSIVE LOSS	$ (42,646,453)	$ (25,114,099)	$ (117,768,147)	$ (75,055,865)
Net loss per share, basic and diluted	$ (0.73)	$ (0.54)	$ (2.03)	$ (1.64)
Weighted average number of shares, basic and diluted	58,128,772	45,716,151	57,832,339	45,687,630

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 (LOSS)	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance at December 31, 2025	57,370,909	$ 57,371	$ 610,330,105	$ 283,154	$ (304,878,485)	$ 305,792,145
Stock-based compensation	—	—	5,918,055	—	—	5,918,055
Stock options exercised	293,764	294	1,470,365	—	—	1,470,659
Unrealized loss on marketable securities	—	—	—	(536,881)	—	(536,881)
Net loss					(33,941,345)	(33,941,345)
Balance at March 31, 2026	57,664,673	$ 57,665	$ 617,718,525	$ (253,727)	$ (338,819,830)	$ 278,702,633
Stock-based compensation	—	—	6,062,925	—	—	6,062,925
Stock options exercised	444,316	444	2,096,356	—	—	2,096,800
Unrealized gain on marketable securities	—	—	—	90,186	—	90,186
Net loss	—	—	—	—	(40,733,654)	(40,733,654)
Balance at June 30, 2026	58,108,989	$ 58,109	$ 625,877,806	$ (163,541)	$ (379,553,484)	$ 246,218,890
Stock-based compensation	—	—	6,103,472	—	—	6,103,472
Stock options exercised	30,000	30	88,670	—	—	88,700
Unrealized gain on marketable securities	—	—	—	9,648	—	9,648
Net loss	—	—	—	—	(42,656,101)	(42,656,101)
Balance at September 30, 2026	58,138,989	$ 58,139	$ 632,069,948	$ (153,893)	$ (422,209,585)	$ 209,764,609

	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
Stock-based compensation	—	—	3,997,348	—	—	3,997,348
Stock options exercised	5,000	5	6,945	—	—	6,950
Unrealized loss on marketable securities	—	—	—	(543,452)	—	(543,452)
Net loss	—	—	—	—	(24,570,647)	(24,570,647)
Balance at September 30, 2025	45,716,975	$ 45,717	$ 357,684,987	$ 844,122	$ (274,707,571)	$ 83,867,255

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	Nine months ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (117,331,100)	$ (74,873,032)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,997,504	1,386,454
Stock-based compensation	18,084,452	13,126,439
Restricted stock awards granted	—	257,461
Amortization/accretion of note premiums/discounts	(1,940,592)	—
Changes in lease liabilities	4,114,733	343,592
Other	8,555	157,519
Changes in operating assets and liabilities:		
Receivables	—	10,309,322
Prepaid expenses and other assets	(124,298)	(768,086)
Accounts payable and accrued expenses	(1,237,464)	3,815,813
Net cash used in operating activities	(96,428,210)	(46,244,518)
Cash flows from investing activities:		
Purchase of marketable securities	(282,317,554)	(136,392,638)
Proceeds from sales and maturities of marketable securities	159,870,145	197,383,098
Purchases of property and equipment	(10,996,566)	(1,239,588)
Proceeds from sales of property and equipment	116,133	—
Payments for leasehold improvements	(905,494)	(383,539)
Payments for construction in progress	(9,264,455)	(4,976,312)
Net cash provided by (used in) investing activities	(143,497,791)	54,391,021
Cash flows from financing activities:		
Payments made for CIRM liability	(6,339,862)	—
Proceeds from exercise of stock options	3,656,159	76,884
Net cash provided by (used in) financing activities	(2,683,703)	76,884
Net increase (decrease) in cash, cash equivalents and restricted cash	(242,609,704)	8,223,387
Cash, cash equivalents and restricted cash balance at beginning of period	287,847,312	11,286,996
Cash, cash equivalents and restricted cash balance at end of period	$ 45,237,608	$ 19,510,383
Supplemental disclosures of cash flow information:		
Interest paid in cash	$ —	$ —
Income taxes paid in cash	$ 1,600	$ 1,600
Initial recognition of right-of-use asset	$ 76,323,671	$ —

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," "Capricor," the "Company," "we," "us" or "our"), is a clinical-stage biotechnology company focused on the development and potential commercialization of transformative cell and exosome-based therapeutics for treating Duchenne muscular dystrophy ("DMD") and other diseases with high unmet medical needs. The Company is a public company and currently trades under the symbol "CAPR" on the Nasdaq Global Select Market.

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 17, 2026, from which the December 31, 2025 consolidated balance sheet was derived. Interim results are not necessarily indicative of the results that may be expected for the year ending December 31, 2026.

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. Management has determined that the Company operates as a single reportable operating segment.

Reclassification

Certain prior period amounts have been reclassified to conform to the current period presentation. Specifically, (i) receivables, previously presented as a separate line item in the consolidated balance sheets, are now included in prepaid expenses and other current assets; (ii) loss on disposal of fixed assets, previously presented as a separate line item in the consolidated statements of operations and comprehensive loss and consolidated statements of cash flows, is now included in other income (loss) and other operating activities, respectively; and (iii) provision for income taxes, previously included in general and administrative expenses, is now presented separately in the consolidated statements of operations and comprehensive loss. These reclassifications had no effect on previously reported total assets, total stockholders' equity, net loss, or net cash used in operating activities.

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 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.

Significant estimates include, but are not limited to, the determination of clinical trial accruals, fair value of stock-based compensation awards, useful lives of long-lived assets, revenue recognition under customer contracts, and the

realizability of deferred tax assets. These estimates are based on historical experience and assumptions that management believes are reasonable; however, actual results may differ from these estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of less than 90 days at the date of purchase to be cash equivalents.

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 several financial institutions. These accounts are insured by the Federal Deposit Insurance Corporation 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.

We are subject to supplier concentration risk, as we rely on a limited number of suppliers for our critical materials. Any disruption in the supply of materials from these key vendors could result in significant delays to our product development timelines and may require us to incur substantial additional costs to secure alternative sources for manufacturing.

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.

Cloud Computing Arrangements ("CCA")

The Company accounts for CCAs in accordance with ASC Topic 350, *Intangibles*, and the capitalized implementation costs associated with these arrangements are included in prepaid expenses and other current assets and other assets on the consolidated balance sheets and are amortized on a straight-line basis over their estimated useful life.

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 ten years. Leasehold improvements are depreciated on a straight-line basis over the shorter of the useful life of the asset or the lease term.

Long-Lived Assets

The Company accounts for the impairment and disposition of long-lived 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.

Leases

The Company accounts for its leases in accordance with ASC Topic 842, *Leases* ("ASC 842"), which requires lessees to recognize most leases on the balance sheet with a corresponding right-of-use asset ("ROU asset") and a lease liability. 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. ROU assets and lease liabilities are recognized at lease commencement based on present value of fixed lease payments over the lease term. Variable payments that do not depend on a rate or index, which usually represent operating expenses associated with the Company's operating leases, are not included in the lease liability and are recognized as they are incurred.

At the inception of an arrangement, the Company evaluates the specific facts and circumstances to determine whether the arrangement constitutes or contains a lease. Leases are classified as either finance or operating leases. The Company's leases are primarily operating leases. The Company elects the short-term lease exemption for leases with a term of twelve months or less.

The Company uses its incremental borrowing rate to measure lease liabilities when the implicit rate is not readily determinable. The Company determines its incremental borrowing rate based on the rate of interest it would have to pay on a collateralized basis to borrow, over a similar term and in a similar economic environment, an amount equal to the lease payments.

The Company has elected the practical expedient to combine lease and non-lease components for real estate leases. This practical expedient is not elected for manufacturing facilities and equipment embedded in product supply arrangements.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), using a five-step model to recognize revenue when control of promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled. The Company's arrangements may include fixed consideration, such as upfront payments and milestones, as well as variable consideration, such as sales-based royalties and shared revenues. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty is resolved.

Revenue is recognized either at a point in time or over time, depending on when control of the promised goods or services is transferred to the customer. For performance obligations satisfied over time, the Company recognizes revenue based on a measure of progress that depicts the transfer of services to the customer. Upfront payments received in advance of performance are recorded as deferred revenue.

Accounts Receivable

Accounts receivable are recorded at invoiced amounts, net of an allowance for credit losses, if any. The Company evaluates the collectability of its accounts receivable and records an allowance when collection is not probable.

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*.

Stock-Based Compensation

The Company accounts for stock-based employee compensation arrangements in accordance with FASB ASC 718, *Compensation – Stock Compensation* and recognizes compensation expense for all share-based payment awards on the grant-date fair value. For time-based awards, expense is recognized over the requisite service period, and for

performance-based options, expense is recognized when the Company determines that achievement of the performance conditions is probable.

Income Taxes

Income taxes are recognized for the amount of taxes payable or refundable for the current year and deferred tax liabilities and assets are recognized for the future tax consequences of transactions that have been recognized in the Company's financial statements or tax returns.

Deferred tax assets are reduced by a valuation allowance when, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

The Company uses guidance issued by the FASB that clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold of more likely than not and a measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In making this assessment, a company must determine whether it is more likely than not that a tax position will be sustained upon examination, based solely on the technical merits of the position, and must assume that the tax position will be examined by taxing authorities.

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

Basic and Diluted Loss per Share

The Company reports earnings per share in accordance with 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.

2. FAIR VALUE MEASUREMENTS

The Company measures certain assets and liabilities in accordance with ASC Topic 820, *Fair Value Measurement*. 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 valuation techniques used to determine the fair value of the Company's Level II financial instruments, which consist primarily of U.S. government agency securities, commercial papers, and corporate bonds, are based on quoted market prices for similar instruments or model-driven valuations utilizing significant inputs derived from or corroborated by observable market data.

The following table summarizes the fair value measurements by level at September 30, 2026 and December 31, 2025 for assets and liabilities measured at fair value on a recurring basis:

	September 30, 2026			
	Level I	Level II	Level III	Total
Cash equivalents				
Money market funds	$ 24,753,548	$ —	$ —	$ 24,753,548
U.S. treasuries	4,984,875	—	—	4,984,875
U.S. government agencies	—	1,997,040	—	1,997,040
Commercial papers	—	1,988,080	—	1,988,080
Marketable securities				
U.S. treasuries	51,806,964	—	—	51,806,964
U.S. government agencies	—	29,854,831	—	29,854,831
Corporate bonds	—	34,929,779	—	34,929,779
Commercial papers	—	36,709,412	—	36,709,412
Total financial assets	$ 81,545,387	$ 105,479,142	$ —	$ 187,024,529

	December 31, 2025			
	Level I	Level II	Level III	Total
Cash equivalents				
Money market funds	$ 12,907,814	$ —	$ —	$ 12,907,814
Marketable securities				
U.S. treasuries	30,281,603	—	—	30,281,603
Total financial assets	$ 43,189,417	$ —	$ —	$ 43,189,417

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.

3. CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES

The following table summarizes the Company's cash, cash equivalents and marketable securities as of September 30, 2026 and December 31, 2025, respectively:

	September 30, 2026			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash and money market funds	$ 35,309,998	$ —	$ —	$ 35,309,998
U.S. treasuries	56,740,976	96,312	(45,449)	56,791,839
U.S. government agencies	31,904,318	—	(52,447)	31,851,871
Corporate bonds	35,007,925	1,119	(79,265)	34,929,779
Commercial papers	38,771,655	—	(74,163)	38,697,492
Total cash, cash equivalents and marketable securities	$ 197,734,872	$ 97,431	$ (251,324)	$ 197,580,979
Classified as:				
Cash and cash equivalents				$ 44,279,993
Short-term marketable securities				153,300,986
Long-term marketable securities				—
Total cash, cash equivalents and marketable securities				$ 197,580,979

	December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash and money market funds	$ 287,847,312	$ —	$ —	$ 287,847,312
U.S. treasuries	29,998,449	283,154	—	30,281,603
Total cash, cash equivalents and marketable securities	$ 317,845,761	$ 283,154	$ —	$ 318,128,915

Classified as:	
Cash and cash equivalents	$ 287,847,312
Short-term investments	30,281,603
Long-term investments	—
Total cash, cash equivalents and marketable securities	$ 318,128,915

The contractual maturities of the Company's available-for-sale securities at September 30, 2026 did not exceed two years.

The Company does not intend to sell these investments for the purpose of realizing losses; however, the securities are classified as available-for-sale and may be sold in response to changes in market interest rates, liquidity needs, or other factors. The Company believes it is more likely than not that it will not be required to sell the investments before recovery of their amortized cost basis. Accordingly, the Company has determined that the available-for-sale securities that were in an unrealized loss position did not have any credit loss impairment as of September 30, 2026.

4. OTHER ASSETS

Cloud Computing Arrangements

The Company capitalizes costs associated with the development of its CCAs, which have estimated useful lives ranging from five to seven years. As of September 30, 2026 and December 31, 2025, capitalized implementation costs totaled approximately $2.1 million and $1.1 million, with $154,851 and $20,800 of accumulated amortization recognized, respectively. Amortization expense totaled $57,999 and $134,051 for the three and nine months ended September 30, 2026, respectively, and there was no amortization expense for the three and nine months ended September 30, 2025.

Restricted Cash

As of September 30, 2026, restricted cash consists of funds held in a savings account pledged as collateral for a standby letter of credit issued as a security deposit for the Company’s lease of 9625 Towne Centre Drive, San Diego, California (the “Towne Centre Premises”). Because the letter of credit is required for the term of the lease, the entire balance is classified as noncurrent and is included within other assets on the condensed consolidated balance sheet. A reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheet that sums to the total of the same amounts shown in the condensed consolidated statement of cash flows is as follows:

	September 30, 2026	December 31, 2025
Cash and cash equivalents	$ 44,279,993	$ 287,847,312
Restricted cash	957,615	—
Total cash, cash equivalents, and restricted cash	$ 45,237,608	$ 287,847,312

5. PROPERTY AND EQUIPMENT

Property and equipment, net consisted of the following:

	September 30, 2026	December 31, 2025
Furniture and fixtures	$ 189,821	$ 189,821
Laboratory equipment	9,597,017	8,056,063
IT equipment	2,053,646	318,858
Manufacturing equipment	8,100,313	675,741
Leasehold improvements	24,172,034	2,785,395
Construction in progress	220,263	11,436,953
Property and equipment, gross	44,333,094	23,462,831
Less accumulated depreciation	(6,719,340)	(5,150,593)
Property and equipment, net	$ 37,613,754	$ 18,312,238

Depreciation was $900,989 and $494,725 for the three months ended September 30, 2026 and 2025, respectively, and $1,997,504 and $1,386,454 for the nine months ended September 30, 2026 and 2025. No impairment related to long-lived assets was recorded for the three and nine months ended September 30, 2026 and 2025.

6. LEASES

Long-Term Operating Leases

San Diego, California

Capricor leases 34,348 square feet of laboratory, manufacturing, and office space located at 10865 Road to the Cure, San Diego, California for our corporate headquarters from Altman Investment Co., LLC (the "Altman Lease"). The lease agreement commenced on October 1, 2021 for an initial lease term of five years. On February 26, 2025, the Company entered into a Fourth Amendment to the Altman Lease (the "Fourth Amendment"), where the rent is subject to a 3.0% annual rent increase commencing October 1, 2026 plus certain operating expenses and taxes. The Fourth Amendment extends the Altman Lease term to September 30, 2033, with an option to renew for an additional term of five years. The Company is not reasonably certain that it will exercise this option to renew and therefore it is not included in ROU assets and liabilities as of September 30, 2026. The Fourth Amendment commenced on July 1, 2025, which resulted in an increase of approximately $13.5 million in operating lease liabilities and $13.4 million in ROU assets. The Altman Lease, as amended, provides for a tenant improvement allowance from the landlord for a total of $1.3 million, all of which was received in 2026. The Company has thus remeasured its lease liability and ROU assets to reflect such allowance.

On May 14, 2026, the Company entered into a License Agreement (the "License Agreement") with ARE-SD Region No. 39 Owner, LLC (the "ARE Landlord"), granting the Company temporary occupancy of approximately 171,000 rentable square feet at the Towne Centre Premises while the parties negotiated a formal lease. Beginning September 1, 2026, the Company began paying approximately $565,000 per month in license fees, operating expenses and administrative rent, which will continue until the formal lease commences.

On July 9, 2026, the Company entered into a Lease Agreement (the "ARE Lease") with the ARE Landlord for the Towne Centre Premises, which will serve as the Company's new corporate headquarters, manufacturing and laboratory facility. The term will commence on the earlier of (i) satisfaction or waiver of the Company's FDA approval contingency (the "Lease Contingency") or (ii) December 31, 2026, with rent commencing twelve months thereafter, and will end 138 months following the rent commencement date, with two options to extend for five years each (the "Extension Rights").

Initial base rent is approximately $958,000 per month, subject to annual increases of 3.0%, plus administrative rent equal to 1% of base rent and variable taxes, insurance and operating costs. Base rent is fully abated for 18 months and partially abated for the following six months. The ARE Landlord will provide a tenant improvement allowance up to approximately $31.6 million (the "TI Allowance"), and the Company will provide a security deposit of approximately $958,000. If the Company does not receive FDA approval of Deramiocel for the treatment of DMD on terms and conditions acceptable to the Company in its sole discretion on or before December 31, 2026, either party may terminate the ARE Lease.

The Towne Centre Premises were made available for the Company's use on May 21, 2026, and the Company concluded, using significant judgment, that the License Agreement and ARE Lease represent a single operating lease that commenced on that date. The Company recognized an ROU asset of approximately $76.3 million and an operating lease liability of approximately $75.5 million, using an incremental borrowing rate of approximately 7.7%. The Extension Rights are excluded from the lease term because the Company is not reasonably certain to exercise them, and the contingent termination right does not limit the lease term because it depends on a future event outside the control of both parties. If the Lease Contingency is not resolved by December 31, 2026, the Company will reassess the lease term. The Company elected the practical expedient not to separate lease and non-lease components.

The Company initially estimated the contractual commencement date to be August 22, 2026, the original Prescription Drug User Fee Act ("PDUFA") target action date for Deramiocel. Following the FDA's extension of the PDUFA target action date to November 22, 2026, the Company updated its estimated contractual and rent commencement dates to November 22, 2026 and November 22, 2027, respectively, and remeasured the lease, resulting in an increase to the lease liability and the ROU asset of approximately $73,000.

Other than amounts available under the License Agreement, the TI Allowance is not available for disbursement until the Lease Contingency is resolved, and any portion not disbursed within 24 months after the lease commencement date is forfeited. Allowances related to Company-owned improvements reduce the ROU asset when determinable and available, and amounts received before the Lease Contingency is resolved are recorded as a liability because they are repayable if the lease is terminated. As of September 30, 2026, no tenant improvement costs had been incurred and no amounts had been received under the TI Allowance.

Los Angeles, California

Capricor leased 1,892 square feet of laboratory, manufacturing and office facilities in Los Angeles, California from Cedars-Sinai Medical Center ("CSMC"), pursuant to a lease entered into in 2014 (the "CSMC Lease"). Capricor subsequently entered into several amendments modifying certain terms of the CSMC Lease. We entered into an amendment effective August 1, 2024, extending the lease term through July 31, 2026, with monthly lease payments of $11,028. The CSMC Lease expired on July 31, 2026, and the Company vacated the premises upon expiration.

Summary of Long-Term Operating Leases

The long-term real estate operating leases are included in lease right-of-use assets, net on the Company's consolidated balance sheet, which totaled $87.1 million and $13.5 million as of September 30, 2026 and December 31, 2025, respectively, and represent the Company's right to use the underlying assets for the lease term. The Company's obligation to make lease payments is included in lease liabilities, current and lease liabilities, net of current on the Company's 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 September 30, 2026:

2026 (remainder)	$ 1,563,320
2027	2,526,801
2028	2,597,663
2029	8,121,909
2030	14,973,807
Thereafter	127,381,348
Total minimum lease payments	157,164,848
Less: imputed interest	(64,934,887)
Total operating lease liabilities	$ 92,229,961
Included in the consolidated balance sheet:	
Current portion of lease liabilities	$ 1,519,196
Lease liabilities, net of current	90,710,765
Total operating lease liabilities	$ 92,229,961
Other Information:	
Weighted average remaining lease term	11.8 years
Weighted average discount rate	7.5%

The following table contains a summary of the lease costs recognized and lease payments pertaining to the Company's operating leases under ASC 842, excluding short-term leases, for the periods indicated:

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Operating lease costs	$ 3,268,633	$ 619,332	$ 5,375,400	$ 1,040,046
Variable lease costs	458,166	284,857	1,120,877	504,361
Lease payments	1,331,316	242,051	2,560,666	696,454

Short-Term Operating Leases

The Company had several short-term lease arrangements for laboratory, manufacturing, and office space in Beverly Hills, Vista, and San Diego, California, all of which terminated during the first half of 2026. Short-term operating lease costs for the three months ended September 30, 2026 and 2025 were $28,394 and $335,980, respectively, and $525,869 and $1,058,456 for the nine months ended September 30, 2026 and 2025.

7. COLLABORATIONS, LICENSES AND REVENUE

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 ("CDCs") with Università Degli Studi Di Roma La Sapienza (the "University of Rome"), Johns Hopkins University ("JHU"), and CSMC. Capricor is also a party to an exclusive license agreement for intellectual property rights related to CDC-derived exosomes with CSMC. In addition, Capricor has filed solely-owned patent applications related to CDC and exosomes technologies developed by its own employees.

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 provided 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, paid minimum annual royalties in the amount of 20,000 Euros per year, and was obligated to pay a lower-end of a mid-range double-digit percentage on all royalties received as a result of sublicenses granted, which were net of any royalties paid to third parties under a license agreement from such third-party to Capricor until expiration of the license. The minimum annual royalties were creditable against future royalty payments.

The Rome License Agreement expired on January 4, 2026.

The Johns Hopkins University 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 the second quarter of 2026, Capricor paid JHU a $500,000 development milestone related to the Phase 3 study pursuant to the terms of the JHU License Agreement. Capricor's next and final development milestone payment will be triggered, if at all, upon receipt of a full FDA market approval, for which a payment of $1,000,000 will be due.

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

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.

Cell Line License Agreement with Life Technologies

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

Revenue Recognition for Collaboration and Distribution Agreements

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 consolidated statements of operations 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 Company also evaluates whether a significant financing component exists in its collaboration agreements. Typically, a significant financing component does not exist because customers pay upfront for services and 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 represent 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 is 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 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.

Commercialization and Distribution Agreement (Nippon Shinyaku - United States)

On January 24, 2022, Capricor entered into a Commercialization and Distribution Agreement (the "U.S. Distribution Agreement") with Nippon Shinyaku, a Japanese corporation 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.

On May 7, 2026, Capricor announced that it had filed a Motion for Preliminary Injunction and Complaint for Equitable Relief (the "Complaint") in the Superior Court of New Jersey. Capricor subsequently withdrew the motion, without prejudice, in order to resolve the dispute through arbitration, and arbitration proceedings have commenced (see Note 15 – "Commitments and Contingencies").

Commercialization and Distribution Agreement (Nippon Shinyaku - 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 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 ASC 606, *Revenue from Contracts with 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 consolidated balance sheets as of September 30, 2026.

Summary of Collaboration Revenue

In total, for the three and nine months ended September 30, 2026 and 2025, the Company did not recognize any revenue from its collaboration and distribution agreements with Nippon Shinyaku, and has no accounts receivable related to such agreements as of September 30, 2026 or December 31, 2025.

As of September 30, 2026 and December 31, 2025, the Company had no deferred revenue related to the U.S. Distribution Agreement. The Company recorded $12.0 million of deferred revenue related to the Japan Distribution Agreement, which represents the upfront payment received for which no performance obligation had been satisfied as of September 30, 2026 or December 31, 2025.

8. RELATED PARTY TRANSACTIONS

Consulting Agreements

In 2013, Capricor entered into a Consulting Agreement (the "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 was terminated effective September 1, 2026. Under this consulting arrangement, the Company incurred consulting fees of $20,000 and $30,000, respectively for the three months ended September 30, 2026 and 2025, and $80,000 and $90,000, respectively, for the nine months ended September 30, 2026 and 2025. As of September 30, 2026 and December 31, 2025, $0 and $10,000 were recorded in accounts payable related to the Consulting Agreement, respectively.

Commercialization and Distribution Agreements

As noted above, Capricor is party to two commercialization and distribution agreements with Nippon Shinyaku, which holds more than 5% of the outstanding capital stock of Capricor Therapeutics based on information supplied in Schedule 13G/A filed with the SEC on September 24, 2024 (see Note 7 – "Collaborations, Licenses and Revenue"). There were no outstanding receivables or payables as of September 30, 2026 or December 31, 2025.

9. GOVERNMENT GRANTS AND OTHER INCOME

CIRM Grant Award

In 2016, Capricor entered into an award agreement with the California Institute for Regenerative Medicine ("CIRM") for approximately $3.4 million to support, in part, the Company's Phase I/II HOPE-Duchenne clinical trial.

The Company accounted for the award as a liability rather than income because the Company had the option to convert the award into a loan. In the second quarter of 2026, the Company entered into a loan repayment agreement with CIRM providing for repayment in two installments. As of September 30, 2026, the Company had fully repaid approximately $6.3 million, consisting of approximately $3.4 million of principal and approximately $2.9 million of accrued interest, satisfying its repayment obligation under the award. Although the CIRM loan has been fully repaid, the Company remains subject to certain reporting and other obligations under the applicable CIRM agreements and policies.

10. ACCRUED EXPENSES AND CLINICAL TRIAL ACCRUALS

Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2026	December 31, 2025
Accrued clinical expenses	$ 2,427,230	$ 2,689,764
Accrued payroll and related costs	7,195,291	6,710,578
Accrued construction in progress costs	—	3,011,034
Other accrued expenses	3,705,384	3,146,270
Total accrued expenses	$ 13,327,905	$ 15,557,646

11. STOCK-BASED COMPENSATION

Stock-Based Compensation

For stock options, the Company estimates the fair value of the awards on the date of grant using an option-pricing model. The portion of the award expected to vest is recognized as expense in the Company's statements of operations and comprehensive loss over the requisite service period for time-based awards and upon determining that the performance condition is probable for performance-based awards. 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.

Warrants

The following table summarizes all warrant activity for the nine months ended September 30, 2026:

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2025	3,345,922	$ 5.70
Granted	—	—
Exercised	—	—
Outstanding at September 30, 2026	3,345,922	$ 5.70

The warrants outstanding at September 30, 2026 expire on October 3, 2030.

Stock Awards

The Company maintains several equity incentive plans. The Company currently grants stock options and restricted stock awards only under the 2020 Equity Incentive Plan, the 2021 Equity Incentive Plan, and the 2025 Equity Incentive Plan (the "2025 Plan"). No new awards are granted under the Company's prior equity plans.

In May 2025, the Company's stockholders approved the 2025 Plan, which authorized 3,500,000 shares of common stock for future awards. The 2025 Plan provides for an annual automatic increase in the number of shares available for issuance on January 1 of each year through 2035, equal to 5% of the Company's outstanding shares of common stock as of the last day of the preceding fiscal year. Accordingly, on January 1, 2026, 2,868,420 shares were added to the 2025 Plan. Following approval of the 2025 Plan, no further automatic share increases will be made to the 2021 Equity Incentive Plan. As of September 30, 2026, 4,434,633 shares remained available for issuance under the Company's equity incentive plans.

The plans are administered by the Board and its compensation committee, which determine the recipients, award types, number of shares, exercise price and vesting terms. Stock options are granted at an exercise price not less than the closing price of the Company's common stock on the grant date, generally vest over one to four years, and have a maximum term of ten years.

Stock Option Awards

The estimated weighted average fair value of the options granted during the three months ended September 30, 2026 and 2025 was approximately $17.92 and $5.50 per share, respectively. The estimated weighted average fair value of the options granted during the nine months ended September 30, 2026 and 2025 was approximately $21.44 and $12.01 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 nine months ended September 30, 2026 and 2025:

	Nine months ended September 30,	
	2026	2025
Expected volatility	113 - 197 %	104 - 115 %
Expected term	1 - 6 years	5 - 6 years
Dividend yield	0 %	0 %
Risk-free interest rates	3.5 - 5.1 %	3.7 - 4.5 %

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

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
General and administrative	$ 2,817,035	$ 1,779,609	$ 8,411,159	$ 6,497,110
Research and development	3,286,437	2,217,739	9,673,293	6,886,790
Total	$ 6,103,472	$ 3,997,348	$ 18,084,452	$ 13,383,900

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 September 30, 2026, the total unrecognized fair value compensation cost related to non-vested stock options was approximately $60.5 million, which is expected to be recognized over a weighted average period of approximately 2.2 years. As of September 30, 2026, the Company had approximately $5.7 million of total unrecognized stock-based compensation expense related to performance-based options subject to the achievement of certain performance conditions over a one-year performance period. Compensation cost associated with these awards will be recognized only if and when the applicable performance conditions are determined to be probable of achievement. As of September 30, 2026, the Company concluded that achievement of the performance conditions was not considered probable, and accordingly, no stock-based compensation expense related to these awards has been recognized.

The following is a schedule summarizing employee and non-employee stock option activity for the nine months ended September 30, 2026:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2025	12,313,107	$ 6.27	
Granted	2,673,200	24.87	
Exercised	(768,080)	4.76	$ 18,734,038
Expired/Cancelled	(618,131)	20.00	
Outstanding at September 30, 2026	13,600,096	$ 9.39	$ 49,482,886
Exercisable at September 30, 2026	9,308,919	$ 5.71	$ 45,208,801

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 Units

The Company has granted restricted stock units ("RSUs") under the 2025 Plan. Each outstanding RSU will be exchanged for one share of the Company's common stock. The Company estimates the fair value of each RSU using the Company's adjusted closing stock price on the grant date.

The following table summarizes the activity of the Company's RSUs for the nine months ended September 30, 2026:

	Number of RSUs	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2025	—	$ —
Granted	15,000	24.81
Vested	—	—
Expired/Cancelled	—	—
Outstanding at September 30, 2026	15,000	$ 24.81

12. STOCKHOLDERS' EQUITY AND ACCUMULATED OTHER COMPREHENSIVE INCOME

December 2025 Underwritten Public Offering

On December 5, 2025, the Company entered into an underwriting agreement with Piper Sandler & Co. and Oppenheimer & Co., Inc. as representatives of the underwriters (the "Underwriters"), pursuant to which the Company agreed to sell and issue, in a public offering an aggregate of 6,000,000 shares of common stock, including the exercise in full of the Underwriters' option to purchase an additional 900,000 shares to cover over allotments, at a public offering price of $25.00 per share for total gross proceeds of approximately $172.5 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 $10.5 million.

September 2025 ATM Program

On September 10, 2025, the Company established an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $150.0 million (the "September 2025 ATM Program"), pursuant to an Equity Distribution Agreement with Piper Sandler and Oppenheimer (collectively, the "Agents"), by which the Agents may sell our common stock at the market prices prevailing at the time of sale. The Agents are entitled to compensation for their services at a commission rate of 3.0% of the gross sales price per share of common stock sold plus reimbursement of certain expenses. Effective December 5, 2025, the Company reduced the maximum offering amount from $150.0 million to $125.0 million.

Through December 31, 2025, the Company sold an aggregate of 2,682,307 shares of common stock under the September 2025 ATM Program at an average price of approximately $28.89 per share for gross proceeds of approximately $77.5 million. The Company paid approximately $2.4 million of aggregated fees related to these sales. From January 1, 2026 through the date of this filing, no additional shares have been sold under the September 2025 ATM Program.

Accumulated Other 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 $42.6 million and $25.1 million for the three months ended September 30, 2026 and 2025, respectively, and $117.8 million and $75.1 million for the nine months ended September 30, 2026 and 2025, respectively. The Company's other comprehensive income (loss) is related to a net unrealized gain (loss) on marketable securities. For the three months ended September 30, 2026 and 2025, the Company's other comprehensive income (loss) was $9,648 and $(543,452), respectively, and $(437,047) and $(182,833) for the nine months ended September 30, 2026 and 2025, respectively.

The following summarizes the changes in accumulated other comprehensive loss:

	Net Unrealized Gains/(Losses) Available-For-Sale Securities	Accumulated Other Comprehensive Income/(Loss)
Outstanding at December 31, 2025	$ 283,154	$ 283,154
Other comprehensive loss	(437,047)	(437,047)
Outstanding at September 30, 2026	$ (153,893)	$ (153,893)

Net Loss and Net Loss Per Share

For the nine months ended September 30, 2026 and 2025, warrants and options to purchase 16,946,018 and 17,748,407 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 nine months ended September 30, 2026 and 2025.

13. INCOME TAXES

Significant judgment is required in determining the Company's provision for income taxes, including the recognition and measurement of deferred tax assets and liabilities and the assessment of the related valuation allowance. Deferred tax assets are recognized for deductible temporary differences and net operating loss carryforwards and are reduced by a valuation allowance if, based on available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

In evaluating the realizability of its deferred tax assets, the Company considers both positive and negative evidence, including cumulative losses in recent periods and the lack of sufficient objectively verifiable future taxable income. Based on this evaluation, the Company concluded that it is more likely than not that its deferred tax assets will not be realized. Accordingly, a full valuation allowance has been recorded as of September 30, 2026 and December 31, 2025.

The Company reassesses the realizability of its deferred tax assets at each reporting period.

14. RECENT ACCOUNTING PRONOUNCEMENTS

Recent Accounting Pronouncements

In December 2025, the FASB issued *ASU 2025-11, Interim Reporting (Topic 270): Narrow-Scope Improvements*, which is intended to improve the navigability of the guidance in ASC 270, Interim Reporting, and clarify when it applies. Under the amendments, an entity is subject to ASC 270 if it provides interim financial statements and notes in accordance with U.S. GAAP. ASU 2025-11 also addresses the form and content of such financial statements, interim disclosures requirements, and establishes a principle under which an entity must disclose events since the end of the last annual reporting period that have a material impact on the entity. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, and early adoption is permitted. The Company is currently evaluating the impact of this ASU on its financial statements.

In September 2025, the FASB issued *ASU 2025-06, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*, which amends the guidance in ASC 350-40, Intangibles – Goodwill and Other – Internal-Use Software. The amendments modernize the recognition and disclosure framework for internal-use software costs, removing the previous "development stage" model and introducing a more judgment-based approach. The ASU is effective for fiscal years beginning after December 15, 2027, and for interim periods within those annual reporting periods, with early adoption permitted. The Company is currently evaluating the impact this guidance will have on its financial statements.

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.

15. COMMITMENTS AND CONTINGENCIES

Legal Contingencies

On July 17, 2025, a putative securities class action was filed in the Southern District of California, naming Capricor Therapeutics, Inc. and the Chief Executive Officer of the Company. 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 by Leonel Zamora 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.

On October 2, 2025, the Company received a Section 220 Shareholder Demand Letter dated September 30, 2025 to inspect and make copies of certain books and records of the Company. The stockholder's demand is related to, among other things, alleged false and misleading statements purportedly made by officers and directors of the Company, as well as the alleged failure to disclose material adverse facts about the Company's business, operations, and prospects.

On November 24, 2025, a second derivative action was filed in the Southern District of California by Michael Rosen 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.

On May 7, 2026, Capricor announced that it had filed a Motion for Preliminary Injunction and Complaint for Equitable Relief (the "Complaint") in the Superior Court of New Jersey. against Nippon Shinyaku Co., Ltd and NS Pharma, Inc. (collectively, "NS") with respect to the distribution of Deramiocel. The Complaint alleged that the defendants named therein, NS, failed to adequately prepare for the commercial launch of Deramiocel in the United States pursuant to the U.S. Distribution Agreement ("Distribution Agreement"), and have otherwise materially breached the terms of the Distribution Agreement. In the Complaint, the Company sought rescission of the Distribution Agreement, declaratory judgment that the Company has the right to distribute Deramiocel directly or through distributors other than NS, and other equitable remedies. Capricor subsequently withdrew its application for a preliminary injunction, without prejudice, having determined that resolving this contractual dispute in arbitration following the FDA's decision would give the parties a more complete regulatory record to work from.

In the arbitration, NS filed a complaint for Breach of Contract against Capricor and demands declaratory and injunctive relief holding that Capricor breached the Distribution Agreement, that the Distribution Agreement remains in full force and effect, and requiring Capricor to perform its obligations thereunder. In the arbitration, Capricor filed counterclaims for breach of contract (repudiation and failure to perform), breach of the implied covenant of good faith and fair dealing, rescission based on mutual mistake, declaration of Capricor's right to distribute Deramiocel, and unjust enrichment, reserving claims for unilateral mistake and frustration of purpose. Capricor seeks damages for NS's breaches and repudiation, declaratory and injunctive relief holding that the Distribution Agreement has been repudiated and/or is

rescinded such that Capricor is entitled to distribute, or hire another company to distribute, Deramiocel, and in the alternative Capricor seeks restitution for unjust enrichment.

On May 20, 2026, Capricor received a shareholder litigation demand from Jennifer Godin, a beneficial owner of Capricor common stock, to take action to remedy alleged breaches of fiduciary duties and other violations of law. The demand alleged false and misleading statements purportedly made by officers and directors of the Company, as well as the alleged failure to disclose material adverse facts about the Company's business, operations, and prospects. No settlement amount has yet been requested.

On July 16, 2026, Mesoblast filed a patent infringement and declaratory judgment action in the District of Delaware against Capricor, alleging unauthorized manufacture, use, sale, and importation of the cardiosphere-derived cell product Deramiocel for the treatment of DMD. The complaint asserts infringement of three patents relating to mesenchymal stem cell compositions, preparations, and methods. Mesoblast alleges direct, induced, and contributory infringement and seeks injunctive relief, damages, attorneys' fees and a declaratory judgment of infringement.

On July 30, 2026, Darren Ngasseu Nkamga, individually and on behalf of all others similarly situated, filed a putative securities class action in United States District Court, Southern District of California against Capricor Therapeutics, Inc. and certain officers of the Company for alleged violations of the Federal Securities Laws, alleging that defendants had made materially false and/or misleading statements regarding the Company’s business, operations and prospects.

On August 7, 2026, a derivative action was filed in the Southern District of California by Michael Rosen naming each of the directors on the Board of Capricor Therapeutics, Inc. and certain officers of the Company. The action alleges, among other things, breaches of fiduciary duties and seeks unspecified damages and certain declaratory relief.

On August 20, 2026, Capricor received a stockholder litigation demand from Maria Barragan, a shareholder of Capricor, to take action to remedy alleged breaches of fiduciary duties and other violations of law and alleging that the officers made false and misleading statements to investors concerning the safety and efficacy data from the Company’s Phase 2 trial.

On September 28, 2026 Robert Novick filed a putative securities class action in the Southern District of California against Capricor, its Chief Executive Officer and its Chief Financial Officer, alleging violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 thereunder.

In 2026, the Company received certain employment-related claims from former employees of the Company.

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 September 30, 2026.

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 – “Collaborations, Licenses and Revenue”).

Additionally, the Company is a party to various agreements with contract research, manufacturing, commercialization 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. As of September 30, 2026, approximately $26.1 million of the Company's outstanding purchase orders represented non-cancellable purchase commitments. In the event the Company seeks to terminate these commitments, it may negotiate alternative arrangements with the applicable counterparties.

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 September 30, 2026.

Workforce Reduction

In September 2026, the Company implemented a workforce reduction affecting approximately 10% of its employees as part of an initiative to reduce operating expenses and better align its resources with its strategic and operational priorities.

In connection with the workforce reduction, the Company recognized approximately $579,000 of one-time termination benefits during the three and nine months ended September 30, 2026, which were recorded within research and development expenses and general and administrative expenses in the accompanying condensed consolidated statements of operations. The Company does not expect to incur material additional costs in connection with the workforce reduction.

16. SEGMENT INFORMATION

The Company operates as a single operating segment. The Company’s Chief Executive Officer, who serves as the Chief Operating Decision Maker (“CODM”), is responsible for allocating resources and assessing performance. The CODM reviews the Company’s operating results on an aggregate basis to make decisions about resource allocation, evaluate financial performance, and manage the overall business. Accordingly, the Company’s operations are managed as one reportable segment focused on the development and commercialization of its therapeutic candidates.

The following table represents consolidated net loss summarized by the significant segment expenses regularly reviewed by the CODM for the three and nine months ended September 30, 2026 and 2025.

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Total revenue	$ —	$ —	$ —	$ —
Research and development expense:				
Compensation and benefits	10,447,119	7,368,920	27,996,906	20,289,890
Duchenne muscular dystrophy program (Deramiocel)	11,492,184	7,310,101	37,577,422	24,854,222
Exosomes platform research	673,485	1,474,937	2,006,309	4,160,004
Other R&D segment expenses (1)	3,057,906	1,740,666	7,369,204	4,435,828
Total research and development expense, excluding non-cash expense	25,670,694	17,894,624	74,949,841	53,739,944
Stock-based compensation expense	3,286,437	2,217,739	9,673,293	6,886,790
Depreciation and amortization	601,257	246,735	1,178,458	695,190
Total research and development expense	29,558,388	20,359,098	85,801,592	61,321,924
General and administrative expense:				
Compensation and benefits	3,869,516	1,534,920	9,244,895	5,175,378
Other G&A segment expenses (2)	8,135,820	2,362,423	20,121,938	5,298,847
Total general and administrative expense, excluding non-cash expense	12,005,336	3,897,343	29,366,833	10,474,225
Stock-based compensation expense	2,817,035	1,779,609	8,411,159	6,497,110
Depreciation and amortization	301,977	247,990	821,625	691,263
Total general and administrative expense	15,124,348	5,924,942	38,599,617	17,662,598
Operating loss	(44,682,736)	(26,284,040)	(124,401,209)	(78,984,522)
Investment income	2,025,886	1,713,499	7,141,687	4,236,393
Other income (expense)	749	(106)	(69,978)	(123,303)
Total non-operating income, net	2,026,635	1,713,393	7,071,709	4,113,090
Loss before income taxes	(42,656,101)	(24,570,647)	(117,329,500)	(74,871,432)
(Provision for) benefit from income taxes	—	—	(1,600)	(1,600)
Net loss	$ (42,656,101)	$ (24,570,647)	$ (117,331,100)	$ (74,873,032)

(1) Other R&D segment expenses primarily include other pipeline development costs, and other facility costs.
(2) Other G&A segment expenses primarily include accounting, legal and other professional fees, consulting expenses, pre-commercial initiatives, business insurance, employee travel, and other facility and information technology costs.

The asset information provided to the CODM for the single operating segment is consistent with the amounts reported in the consolidated balance sheets.

17. SUBSEQUENT EVENTS

The Company has evaluated subsequent events occurring after the balance sheet date through the date of this filing. Based on this evaluation, 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 included in 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, under Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q and under the heading "Special Note Regarding Forward-Looking Statements" in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements.

Company Overview

Capricor Therapeutics, Inc. is a biotechnology company focused on the development and potential commercialization of cell and exosome-based therapeutics for the treatment of Duchenne muscular dystrophy ("DMD"), a rare genetic disorder characterized by progressive muscle degeneration and premature death, as well as other diseases with significant unmet medical need. Since our inception, we have devoted substantial resources to the development of our lead product candidate, Deramiocel, an investigative cellular therapy aimed to treat the skeletal and cardiac muscle complications associated with DMD, developing manufacturing capabilities and supporting our research and development activities. Our Biologics License Application ("BLA"), as amended, for Deramiocel for the treatment of DMD is currently under review by the U.S. Food and Drug Administration ("FDA") for potential approval in the United States, with a current Prescription Drug User Fee Act ("PDUFA") target action date of November 22, 2026. We currently have no products approved for commercial sale. Our ability to generate product revenue and achieve profitability will depend on the successful development, regulatory approval and commercialization of Deramiocel and any other product candidates we may develop.

Cell Therapy (Deramiocel)

Our core program is focused on the development and commercialization of Deramiocel, an investigative cellular therapy comprised of cardiosphere-derived cells ("CDCs"), a population of cardiac-derived stromal cells isolated from qualified donated human hearts. Deramiocel is designed to slow disease progression in DMD through immunomodulatory, anti-inflammatory and anti-fibrotic activities of CDCs. These effects are mediated in part by exosomes secreted by CDCs that contain bioactive molecules, including microRNAs and other signaling factors, which may influence gene expression and cellular pathways involved in inflammation, fibrosis, and tissue repair.

Our clinical development program for Deramiocel has focused on adolescents and young adults with DMD, including many patients who are non-ambulatory and experiencing progressive skeletal and cardiac muscle decline. Capricor has administered over 1,300 intravenous infusions across our clinical program to approximately 125 patients with DMD in three separate clinical trials. We believe therapies that address inflammatory and fibrotic processes contributing to muscle degeneration may provide potential benefit across a broad population of individuals with DMD.

Exosomes Platform Technology (StealthX™)

Extracellular vesicles ("EVs"), including exosomes and microvesicles, are nano-scale membrane-enclosed vesicles secreted by many cell types that contain characteristic lipids, proteins and nucleic acids, including messenger RNA and microRNAs. These vesicles facilitate intercellular communication through the binding and activation of membrane receptors or through the delivery of molecular cargo into target cells. Through these mechanisms, EVs may influence a variety of biological processes, including cell survival, proliferation, inflammation and tissue repair.

Exosomes in particular have attracted increasing interest as potential therapeutic and diagnostic platforms. Their small size, generally low immunogenicity, and ability to deliver biologically active molecules to recipient cells may allow

them to modulate complex biological pathways. Because exosomes are cell-free vesicles, they may be stored, handled, and administered using approaches similar to those used for certain established biologic therapies.

Our exosome platform is supported by internal research and external collaborations. Our collaborations and research around exosomes include the National Institutes of Health, the National Institute of Allergy and Infectious Diseases ("NIAID"), JHU, the Department of Defense, the U.S. Army Institute of Surgical Research, and CSMC. Our platform leverages advances in RNA biology, protein engineering and targeted delivery technologies to support the development of exosome-based therapeutics and vaccines. We are currently exploring exosome-based approaches for infectious diseases, monogenic diseases and other potential indications.

To prioritize our resources on Deramiocel, we have moderated the pace of internal development of programs not directly related to Deramiocel, including our exosome-based platform, and expect to continue to do so pending further regulatory clarity. Our current strategy is to advance these programs primarily through collaborations and partnerships that may provide additional development resources and capital to support potential clinical development.

Our Pipeline – Key Programs

Deramiocel: Duchenne Muscular Dystrophy Program: Deramiocel is Capricor's lead product candidate and is being developed for the treatment of DMD, a rare, progressive genetic disease characterized by degeneration of skeletal and cardiac muscle.

Deramiocel's mechanism of action is distinct from mutation-targeted approaches such as exon-skipping oligonucleotides and gene therapies, which aim to restore dystrophin expression in muscle cells. DMD is caused by mutations in the dystrophin gene that impair production of functional dystrophin, a structural protein important for maintaining muscle integrity. Without functional dystrophin, muscle fibers are repeatedly damaged during contraction. This leads to chronic inflammation, muscle cell death and the progressive replacement of muscle tissue with fat and fibrosis. In skeletal muscle, the result is progressive weakness and loss of motor function, typically leading to loss of ambulation and, over time, loss of upper limb function. Loss of upper limb function limits patients' ability to perform daily activities such as eating, grooming and self-care. Respiratory muscle weakness also develops as the disease advances. The heart is affected as well: patients with DMD develop progressive cardiomyopathy, which can lead to heart failure, a leading cause of mortality in DMD. While several therapies have been developed to address certain genetic mutations associated with DMD, significant unmet medical need remains, particularly in patients with established skeletal and cardiac muscle disease.

We have conducted a comprehensive clinical development program evaluating Deramiocel in patients with DMD, including randomized controlled trials and long-term follow-up studies designed to assess safety and efficacy across multiple measures of disease progression. These studies include the Phase 3 HOPE-3 trial, the Phase 2 HOPE-2 trial and each of their ongoing open-label extension studies, and the earlier Phase 1/2 HOPE-Duchenne clinical trial.

Biologics License Application: In late 2024, we completed our submission of a BLA to the FDA seeking approval of Deramiocel for the treatment of DMD. The FDA accepted the BLA for review, granted Priority Review, and assigned a PDUFA target action date of August 31, 2025. In July 2025, we received a Complete Response Letter ("CRL") from the FDA stating that the application did not meet the statutory requirement for substantial evidence of effectiveness and requesting additional clinical data.

Following a Type A meeting with the FDA in August 2025, we aligned with the FDA on a regulatory path forward to address the CRL, including the submission of additional clinical data from the Phase 3 HOPE-3 trial. We subsequently submitted our response to the CRL, which the FDA accepted as a complete response and classified as a Class 2 resubmission, assigning a new PDUFA target action date of August 22, 2026.

Advisory Committee Meeting: On July 29, 2026, the FDA held a meeting of the Cellular, Tissue and Gene Therapies Advisory Committee (the "Ad-Com Committee") where the Ad-Com Committee heard the respective positions of the FDA and the Company with respect to the data presented to the FDA. The Ad-Com Committee voted 3 in favor and 9 against on whether available evidence provides substantial evidence of effectiveness of Deramiocel for the treatment of

cardiomyopathy in patients with DMD. The Ad-Com Committee was not asked to vote on the HOPE-3 primary endpoint of skeletal-muscle function or on overall benefit-risk. In a separate discussion of upper limb function with members of the Ad-Com Committee, we believe the members' feedback was directionally supportive of the HOPE-3 clinical evidence of skeletal-muscle function. The Ad-Com Committee's recommendation is advisory only and is not binding on the FDA.

Major Amendment to the BLA: Following the Ad-Com Committee meeting, in August 2026, we submitted an amendment to the BLA that included 24-month data from the open-label extension of the HOPE-3 trial, together with additional analyses of the existing data package, in support of a refined proposed indication for the treatment of upper limb impairment in patients with DMD aged > 9 years old, consistent with the population and primary endpoint of HOPE-3. The FDA classified the submission as a major amendment and extended the PDUFA target action date by three months, to November 22, 2026. We believe that we have submitted all information requested by the FDA to date; however, the FDA may request additional information or analyses at any time during its review.

Bioresearch Monitoring Inspection: In July 2026, as part of its review of the BLA, the FDA conducted a Bioresearch Monitoring ("BIMO") inspection relating to the conduct of our clinical trials and issued a Form FDA 483 containing one inspectional observation relating primarily to the Company's standard operating procedures, documentation practices, vendor oversight, and audit report timeliness in connection with the conduct of the HOPE-3 clinical trial. The Company does not believe the observation affects the integrity or reliability of the HOPE-3 data. We have submitted our response to the FDA and are awaiting the Agency's feedback.

Recent Clinical Data: In July 2026, the full results of the HOPE-3 trial were published in *The Lancet* following independent peer review. As reported, HOPE-3 met its primary endpoint, demonstrating a statistically significant treatment difference versus placebo in change from baseline in the Performance of the Upper Limb, version 2.0 ("PUL 2.0") total score at 12 months (p=0.029), reflecting a slowing of upper limb disease progression. Results on additional functional and cardiac measures were nominally significant under the trial's prespecified hierarchical testing procedure. In October 2026, we presented 24-month data from the HOPE-3 open-label extension ("OLE") at the 31st World Muscle Society Congress. In the OLE, patients originally randomized to placebo who received Deramiocel in the second year showed a 76% slowing in the rate of upper limb decline as measured by PUL 2.0, relative to their first year on placebo (difference of 1.56 points; 95% confidence interval 0.47 to 2.64). The OLE analyses are open-label, were not powered for statistical comparison, had no alpha allocated and are descriptive in nature. In November 2026, the HOPE-3 cardiac results, including a comparison to external natural history data, were presented at the American Heart Association Scientific Sessions 2026. In HOPE-3, Deramiocel was associated with reduced progression of myocardial fibrosis and with a difference in left ventricular ejection fraction of approximately 2.8 percentage points favoring Deramiocel versus placebo in patients with cardiomyopathy at baseline (nominal p=0.0165), each of which was a nominally significant secondary or subgroup analysis.

Manufacturing and Commercial Readiness: Our current Good Manufacturing Practice ("cGMP") manufacturing facility in San Diego, California is operational and, if Deramiocel is approved, is intended to support initial commercial supply. We are expanding the facility to add cleanroom capacity, with validation targeted for the first half of 2027; however, the timing and outcome of these activities are subject to risks and uncertainties, including FDA inspection and approval. We have also undertaken commercial launch planning activities, including with respect to distribution, patient support, market access, reimbursement, medical affairs and physician education.

In parallel with our U.S. regulatory activities, we have initiated regulatory engagement in Europe and Japan and are working with the relevant health authorities to determine the most appropriate regulatory pathway for Deramiocel in those regions. Expansion of our clinical program into younger patients with DMD and into Becker muscular dystrophy remains an area of focus; however, the initiation of any such trials will depend on the outcome of the U.S. regulatory process for Deramiocel.

StealthX™ Exosome Platform: Our StealthX™ exosome platform program consists of engineered exosomes for vaccine and therapeutic development.

Exosome Platform: Engineered Exosome-Based Vaccines: The StealthX™ vaccine is a proprietary vaccine developed internally by Capricor utilizing exosomes that were engineered to express either spike or nucleocapsid proteins

on the surface. Preclinical results from murine and rabbit models published in the peer-reviewed journal, Microbiology Spectrum, showed the StealthX™ vaccine resulted in robust antibody production, potent neutralizing antibodies, a strong T-cell response and a favorable safety profile. We were selected to be part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines providing broader and more durable protection for COVID-19. As part of Project NextGen, NIAID conducted a Phase 1 clinical study with our StealthX™ vaccine. Preliminary data indicated the StealthX™ vaccine has been generally well tolerated and demonstrated a favorable safety profile across all dose levels tested. Early analyses showed limited neutralizing antibody responses at the evaluated dose levels, which may reflect prior vaccination or infection among trial participants. Final results from the trial, including cellular immune response data, are anticipated in the first half of 2027, subject to finalization of the study by NIAID.

Exosome Platform: Engineered Exosome-Based Therapeutics: We are focused on developing a precision-engineered exosome platform technology that has the potential to deliver defined sets of effector molecules that exert their effects through defined mechanisms of action. Pending further regulatory clarity for our DMD program, we plan to continue to explore the use of our proprietary StealthX™ exosome platform for a broad range of therapeutic applications including targeted RNA, protein and small molecule therapeutics to treat or prevent a variety of diseases.

These programs represent our core technology and products.

Financial Operations Overview

As of September 30, 2026, we had cash, cash equivalents, restricted cash, and marketable securities totaling approximately $198.5 million. Since our inception, we have received approximately $600 million through a combination of equity financings, strategic collaborations, grants and other non-dilutive funding sources.

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 $42.7 million and approximately $24.6 million, for the three months ended September 30, 2026 and 2025, respectively. Our net losses were approximately $117.3 million and approximately $74.9 million, for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of approximately $422.2 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 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. The timing and scale of any commercial launch expenditures, and our ability to access capital on favorable terms, may be affected by the outcome of the FDA's review of our BLA.

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. 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 and potential commercialization 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 the U.S. Distribution Agreement and the Japan Distribution Agreement. 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 and the outcome of our dispute against NS.

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 and nine months ended September 30, 2026 and 2025 was zero.

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 September 30,			
	2026	2025	Change ($)	Change (%)
Compensation and other personnel expenses	$ 10,447,119	$ 7,368,920	$ 3,078,199	42 %
Duchenne muscular dystrophy program (Deramiocel)	11,492,184	7,310,101	4,182,083	57 %
Exosomes platform research	673,485	1,474,937	(801,452)	(54)%
Facility expenses	2,681,489	1,540,560	1,140,929	74 %
Stock-based compensation	3,286,437	2,217,739	1,068,698	48 %
Depreciation and amortization	601,257	246,735	354,522	144 %
Research and other	376,417	200,106	176,311	88 %
Total research and development expenses	$ 29,558,388	$ 20,359,098	$ 9,199,290	45 %

R&D expenses for the three months ended September 30, 2026 increased by approximately $9.2 million, or 45%, compared to the three months ended September 30, 2025. The increase was primarily driven by the following:

- $3.1 million increase in compensation and other personnel expenses primarily due to increases in headcount;
- $4.2 million increase in DMD (Deramiocel) program-related expenses primarily related to expanded manufacturing production, and commercial-related expenses for Deramiocel in preparation for potential commercial launch;
- $1.1 million increase in facility expenses primarily related to expanded leased space and incremental equipment and services to support those facilities; and
- $1.1 million increase in stock-based compensation expense primarily due to increases in headcount and stock price.

The increase was partially offset by a $0.8 million decrease in research expenses related to our exosomes platform, primarily related to timing of research activities for exosomes.

	Nine months ended September 30,			
	2026	2025	Change ($)	Change (%)
Compensation and other personnel expenses	$ 27,996,906	$ 20,289,890	$ 7,707,016	38 %
Duchenne muscular dystrophy program (Deramiocel)	37,577,422	24,854,222	12,723,200	51 %
Exosomes platform research	2,006,309	4,160,004	(2,153,695)	(52)%
Facility expenses	6,365,128	3,841,453	2,523,675	66 %
Stock-based compensation	9,673,293	6,886,790	2,786,503	40 %
Depreciation and amortization	1,178,458	695,190	483,268	70 %
Research and other	1,004,076	594,375	409,701	69 %
Total research and development expenses	$ 85,801,592	$ 61,321,924	$ 24,479,668	40 %

R&D expenses for the nine months ended September 30, 2026 increased by approximately $24.5 million, or 40%, compared to the nine months ended September 30, 2025. The increase was primarily driven by the following:

- $7.7 million increase in compensation and other personnel expenses primarily due to increases in headcount;
- $12.7 million increase in DMD (Deramiocel) program-related expenses primarily related to expanded manufacturing production, and commercial-related expenses for Deramiocel in preparation for potential commercial launch;
- $2.5 million increase in facility expenses primarily related to expanded leased space and incremental equipment and services to support those facilities; and
- $2.8 million increase in stock-based compensation expense primarily due to increases in headcount and stock price.

The increase was partially offset by a $2.2 million decrease in research expenses related to our exosomes platform, primarily related to timing of research activities for exosomes.

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 September 30,			
	2026	2025	Change ($)	Change (%)
Stock-based compensation	$ 2,817,035	$ 1,779,609	$ 1,037,426	58 %
Compensation and other personnel expenses	3,869,516	1,534,920	2,334,596	152 %
Professional services	3,467,372	1,040,843	2,426,529	233 %
Facility expenses	2,856,044	189,415	2,666,629	1,408 %
Depreciation and amortization	301,977	247,990	53,987	22 %
Other corporate expenses	1,812,404	1,132,165	680,239	60 %
Total general and administrative expenses	$ 15,124,348	$ 5,924,942	$ 9,199,406	155 %

G&A expenses for the three months ended September 30, 2026 increased by approximately $9.2 million, or 155%, compared to the three months ended September 30, 2025. The increase was primarily driven by the following:

- $1.0 million increase in stock-based compensation primarily due to increases in headcount and stock price;
- $2.3 million increase in compensation and other personnel expenses related to increases in headcount;
- $2.4 million increase in professional services largely attributable to increased legal and consulting costs related to our continuing regulatory and pre-commercial initiatives;

- $2.7 million increase in facility expenses primarily related to expanded leased space and incremental equipment and services to support those facilities; and
- $0.7 million increase in other corporate expenses primarily related to other supporting costs incurred to support pre-commercial initiatives.

	Nine months ended September 30,			
	2026	2025	Change ($)	Change (%)
Stock-based compensation	$ 8,411,159	$ 6,497,110	$ 1,914,049	29 %
Compensation and other personnel expenses	9,244,895	5,175,378	4,069,517	79 %
Professional services	10,828,656	1,817,677	9,010,979	496 %
Facility expenses	4,707,303	344,704	4,362,599	1,266 %
Depreciation and amortization	821,625	691,263	130,362	19 %
Other corporate expenses	4,585,979	3,136,466	1,449,513	46 %
Total general and administrative expenses	$ 38,599,617	$ 17,662,598	$ 20,937,019	119 %

G&A expenses for the nine months ended September 30, 2026 increased by approximately $20.9 million, or 119%, compared to the nine months ended September 30, 2025. The increase was primarily driven by the following:

- $1.9 million increase in stock-based compensation primarily due to increases in headcount and stock price;
- $4.1 million increase in compensation and other personnel expenses related to increases in headcount;
- $9.0 million increase in professional services largely attributable to increased legal and consulting costs related to our continuing regulatory and pre-commercial initiatives;
- $4.4 million increase in facility expenses primarily related to expanded leased space and incremental equipment and services to support those facilities; and
- $1.4 million increase in other corporate expenses primarily related to other supporting costs incurred to support pre-commercial initiatives.

Other Income (Expense)

Investment Income. Investment income for the three months ended September 30, 2026 and 2025 was approximately $2.0 million and $1.7 million, respectively. Investment income for the nine months ended September 30, 2026 and 2025 was approximately $7.1 million and $4.2 million, respectively. The increase in investment income for the three and nine months ended September 30, 2026 as compared to the three and nine months ended September 30, 2025 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, commercial, and research activities, including expenses related to scale-up for potential commercial scale manufacturing if our Deramiocel product is approved. For the first nine months of 2026, we spent approximately $41.9 million on our Deramiocel program. This amount excludes personnel costs. The Company expects to provide additional guidance on its longer-term financial outlook for this program following greater regulatory clarity, which will inform future strategic and capital allocation decisions.

Exosome Platform – Our exosome platform is in early-stage development. For the first nine months of 2026, we spent approximately $2.2 million on our exosome program, primarily related to research, preclinical studies and manufacturing costs associated with our NIAID program. This amount excludes personnel costs. We are prioritizing capital toward Deramiocel and are minimizing expenses related to the exosome platform until further regulatory clarity is obtained with respect to our DMD program.

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/or strategic partners. In particular, our expenditures on the commercialization of Deramiocel, if approved, will depend on the outcome of our dispute with NS and, if we are successful

in such dispute, whether we commercialize Deramiocel in the United States directly or through one or more distributors. 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 September 30, 2026 and December 31, 2025 and our net increase (decrease) in cash, cash equivalents, and restricted cash for the nine months ended September 30, 2026 and 2025 and is intended to supplement the more detailed discussion that follows. The amounts stated in the tables below are expressed in thousands. We believe that our current cash, cash equivalents, and marketable securities are sufficient to fund our operating capital requirements for at least the next twelve months from the issuance date of these condensed consolidated financial statements. For information regarding our material cash requirements, including obligations under our lease and related license agreement for our new headquarters, manufacturing and laboratory facility and our outstanding purchase commitments, see Note 6 – "Leases" and Note 15 – "Commitments and Contingencies" to our condensed consolidated financial statements.

Liquidity and capital resources	September 30, 2026	December 31, 2025
Cash and cash equivalents	$ 44,280	$ 287,847
Marketable securities	$ 153,301	$ 30,282
Restricted cash	$ 958	$ -
Working capital	$ 172,357	$ 287,103
Stockholders' equity	$ 209,765	$ 305,792

	Nine months ended September 30,	
Cash flow data	2026	2025
Cash provided by (used in):		
Operating activities	$ (96,428)	$ (46,245)
Investing activities	(143,498)	54,391
Financing activities	(2,684)	77
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (242,610)	$ 8,223

Our total cash, cash equivalents, restricted cash, and marketable securities as of September 30, 2026 were approximately $198.5 million compared to approximately $318.1 million as of December 31, 2025. The decrease in cash, cash equivalents, restricted cash, and marketable securities from December 31, 2025 to September 30, 2026 is primarily due to our continuing efforts in preparing the Company for potential commercialization. As of September 30, 2026, we had approximately $120.6 million in total liabilities, consisting of approximately $92.2 million in lease liabilities, approximately $16.4 million in accounts payable and accrued expenses, and $12.0 million in deferred revenue, with net working capital of approximately $172.4 million.

Cash used in operating activities was approximately $96.4 million and approximately $46.2 million for the nine months ended September 30, 2026 and 2025, respectively. The increase of approximately $50.2 million in cash used in

operating activities is due to an approximately $42.5 million increase in net loss for the nine months ended September 30, 2026 as compared to the same period in 2025. Furthermore, there was a decrease of approximately $10.3 million in the change in receivables balances, as well as approximately $5.1 million in the change in accounts payable and accrued expenses balances for the nine months ended September 30, 2026 as compared to the same period in 2025. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, including if we expand our platform technology portfolio, engage in further research and development activities, and, in particular, conduct preclinical studies and clinical trials, we expect to continue incurring substantial losses.

We had cash flow used in investing activities of approximately $143.5 million for the nine months ended September 30, 2026 and cash flow provided by investing activities of approximately $54.4 million for the nine months ended September 30, 2025. The change in investing activities for the nine months ended September 30, 2026 as compared to the same period of 2025 is due to the net effect from purchases, sales and maturities of marketable securities and the purchase of approximately $21.2 million in property and equipment, leasehold improvements and construction in progress in the nine months ended September 30, 2026, compared to approximately $6.6 million in the nine months ended September 30, 2025.

We had cash flow used in financing activities of approximately $2.7 million and cash flow provided by financing activities of approximately $0.1 million for the nine months ended September 30, 2026 and 2025, respectively. The change in cash provided by (used in) financing activities for the nine months ended September 30, 2026 as compared to the nine months ended September 30, 2025 is primarily due to payments made for CIRM liability, partially offset by the net proceeds from the exercises of stock options.

From inception through September 30, 2026, we financed our operations primarily through private and public sales of our equity securities, government grants, and payments from distribution agreements and collaboration partners.

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, regulatory, commercial, and research activities;
- the number and scope of our clinical and research programs;
- the costs involved in preparation for the potential commercialization of our Deramiocel product for the treatment of DMD;
- 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 associated with legal matters, including disputes and pending securities litigation, derivative actions and employment claims brought against us;
- 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 (Nippon Shinyaku - United States)

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

On May 7, 2026, Capricor announced that it had filed a Motion for Preliminary Injunction and Complaint for Equitable Relief (the "Complaint") in the Superior Court of New Jersey. against Nippon Shinyaku Co., Ltd and NS Pharma, Inc. (collectively, "NS") with respect to the distribution of Deramiocel. The Complaint alleged that the defendants named therein, NS, failed to adequately prepare for the commercial launch of Deramiocel in the United States pursuant to the U.S. Distribution Agreement ("Distribution Agreement"), and have otherwise materially breached the terms of the Distribution Agreement. In the Complaint, the Company sought rescission of the Distribution Agreement, declaratory judgment that the Company has the right to distribute Deramiocel directly or through distributors other than NS, and other equitable remedies. Capricor subsequently withdrew its application for a preliminary injunction, without prejudice, having determined that resolving this contractual dispute in arbitration following the FDA's decision would give the parties a more complete regulatory record to work from.

In the arbitration, NS filed a complaint for Breach of Contract against Capricor and demands declaratory and injunctive relief holding that Capricor breached the Distribution Agreement, that the Distribution Agreement remains in full force and effect, and requiring Capricor to perform its obligations thereunder. In the arbitration, Capricor filed counterclaims for breach of contract (repudiation and failure to perform), breach of the implied covenant of good faith and fair dealing, rescission based on mutual mistake, declaration of Capricor's right to distribute Deramiocel, and unjust enrichment, reserving claims for unilateral mistake and frustration of purpose. Capricor seeks damages for NS's breaches and repudiation, declaratory and injunctive relief holding that the Distribution Agreement has been repudiated and/or is rescinded such that Capricor is entitled to distribute, or hire another company to distribute, Deramiocel, and in the alternative Capricor seeks restitution for unjust enrichment.

Commercialization and Distribution Agreement (Nippon Shinyaku - Japan)

On February 10, 2023, Capricor entered into 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 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.

Financing Activities by the Company

December 2025 Underwritten Public Offering

On December 5, 2025, the Company entered into an underwriting agreement with Piper Sandler & Co. and Oppenheimer & Co., Inc. as representatives of the Underwriters, pursuant to which the Company agreed to sell and issue, in a public offering an aggregate of 6,000,000 shares of common stock, including the exercise in full of the Underwriters' option to purchase an additional 900,000 shares to cover over allotments, at a public offering price of $25.00 per share for total gross proceeds of approximately $172.5 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 $10.5 million.

September 2025 ATM Program

On September 10, 2025, the Company established the September 2025 ATM Program under a prospectus supplement for aggregate sales proceeds of up to $150.0 million, pursuant to an Equity Distribution Agreement with the Agents by which the Agents may sell our common stock at the market prices prevailing at the time of sale. The Agents are entitled to compensation for their services at a commission rate of 3.0% of the gross sales price per share of common stock sold plus reimbursement of certain expenses. Effective December 5, 2025, the Company reduced the maximum offering amount from $150.0 million to $125.0 million.

Through December 31, 2025, the Company sold an aggregate of 2,682,307 shares of common stock under the September 2025 ATM Program at an average price of approximately $28.89 per share for gross proceeds of approximately $77.5 million. The Company paid approximately $2.4 million of aggregated fees related to these sales. From January 1, 2026 through the date of this filing, no additional shares have been sold under the September 2025 ATM Program.

CIRM Grant Award

In 2016, Capricor entered into an award agreement with the California Institute for Regenerative Medicine ("CIRM") for approximately $3.4 million to support, in part, the Company's Phase I/II HOPE-Duchenne clinical trial.

The Company accounted for the award as a liability rather than income because the Company had the option to convert the award into a loan. In the second quarter of 2026, the Company entered into a loan repayment agreement with CIRM providing for repayment in two installments. As of September 30, 2026, the Company had fully repaid approximately $6.3 million, consisting of approximately $3.4 million of principal and approximately $2.9 million of accrued interest, satisfying its repayment obligation under the award. Although the CIRM loan has been fully repaid, the Company remains subject to certain reporting and other obligations under the applicable CIRM agreements and policies.

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 U.S. GAAP. 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

The Company accounts for its leases in accordance with ASC Topic 842, *Leases* ("ASC 842"), which requires lessees to recognize most leases on the balance sheet with a corresponding ROU asset and a lease liability for most leases. 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. ROU assets and lease liabilities are recognized at lease commencement based on present value of fixed lease payments over the lease term.

Leases are classified as either finance or operating leases. The Company's leases are primarily operating leases. The Company elects the short-term lease exemption for leases with a term of twelve months or less.

The Company uses its incremental borrowing rate to measure lease liabilities when the implicit rate is not readily determinable. The Company determines its incremental borrowing rate based on the rate of interest it would have to pay on a collateralized basis to borrow, over a similar term and in a similar economic environment, an amount equal to the lease payments.

The Company has elected the practical expedient to combine lease and non-lease components for real estate leases. This practical expedient is not elected for manufacturing facilities and equipment embedded in product supply arrangements.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), using a five-step model to recognize revenue when control of promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled. The Company's arrangements may include fixed consideration, such as upfront payments and milestones, as well as variable consideration, such as sales-based royalties and shared revenues. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty is resolved.

Revenue is recognized either at a point in time or over time, depending on when control of the promised goods or services is transferred to the customer. For performance obligations satisfied over time, the Company recognizes revenue based on a measure of progress that depicts the transfer of services to the customer. Upfront payments received in advance of performance are recorded as deferred revenue.

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 related to stock options and restricted stock awards granted to employees, directors and consultants. The Company has six equity plans; however, it currently issues awards only under the 2020 Equity Incentive Plan, the 2021 Equity Incentive Plan, and the 2025 Plan. The Company no longer issues awards under the 2006 Stock Option Plan, the 2012 Restated Equity Incentive Plan or the 2012 Non-Employee Director Stock Option 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 G&A expense or R&D expense, as applicable, in the condensed consolidated statements of operations and comprehensive 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 December 2025, the FASB issued *ASU 2025-11, Interim Reporting (Topic 270): Narrow-Scope Improvements*, which is intended to improve the navigability of the guidance in ASC 270, Interim Reporting, and clarify when it applies. Under the amendments, an entity is subject to ASC 270 if it provides interim financial statements and notes in accordance with U.S. GAAP. ASU 2025-11 also addresses the form and content of such financial statements, interim disclosures requirements, and establishes a principle under which an entity must disclose events since the end of the last annual reporting period that have a material impact on the entity. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, and early adoption is permitted. The Company is currently evaluating the impact of this ASU on its financial statements.

In September 2025, the FASB issued *ASU 2025-06, Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*, which amends the guidance in ASC 350-40, Intangibles – Goodwill and Other – Internal-Use Software. The amendments modernize the recognition and disclosure framework for internal-use software costs, removing the previous "development stage" model and introducing a more judgment-based approach. The ASU is effective for fiscal years beginning after December 15, 2027, and for interim periods within those annual reporting periods, with early adoption permitted. The Company is currently evaluating the impact this guidance will have on its financial statements.

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, cash equivalents, and restricted cash. As of September 30, 2026, the fair value of our cash, cash equivalents, restricted cash, and marketable securities was approximately $198.5 million. Additionally, as of September 30, 2026, Capricor's investment portfolio was classified as cash, cash equivalents, restricted cash, and marketable securities, which consisted primarily of bank checking and savings accounts, money market funds and bank money market accounts, commercial papers, corporate bonds, U.S. treasuries and government agency bonds.

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. 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 the relatively short-term nature of the investments that the Company holds, 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 (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit 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. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. In designing and evaluating the disclosure controls and procedures, management recognizes that controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives.

As required by Rules 13a-15(b) and 15d-15(b) under 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 that evaluation, 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 Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings.

The information set forth under "Legal Contingencies" in Note 15 – "Commitments and Contingencies", to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q is incorporated herein by reference.

Item 1A. Risk Factors.

Part I, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 17, 2026, 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. Other than the addition of, and modifications to, the risk factors listed below, there have been no material changes from the risk factors previously described under Part I, Item 1A of the Form 10-K and under Part II, Item 1A of our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2026 and June 30, 2026.

Risks Related to Our Business

The negative vote of the FDA's Cellular, Tissue and Gene Therapies Advisory Committee is expected to have a significant impact on Deramiocel's approvability in the U.S. for the treatment of cardiomyopathy in patients with DMD.

On July 29, 2026, the FDA convened the Ad-Com Committee to review our BLA for Deramiocel. The single voting question presented to the Ad-Com Committee asked whether the available evidence supports the effectiveness of Deramiocel for the treatment of cardiomyopathy in patients with DMD. The Ad-Com Committee voted 3 in favor and 9 against, with no abstentions. The voting question addressed a narrower indication than we had proposed and did not include a vote on the HOPE-3 primary endpoint of upper limb function or on the overall benefit-risk profile of Deramiocel. With the approval of the FDA, we submitted an amendment to our BLA, which the FDA has indicated it is willing to review; however, we do not know how long it will take for the FDA to make a decision on our BLA. The FDA may give us a CRL (rejecting our amended BLA) or further delay approval of our amended BLA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information. The FDA also extended the PDUFA target action date to November 22, 2026.

We may not be successful in our dispute with NS, and the dispute could result in substantial costs, diversion of resources and harm to our business.

We filed the Complaint in the Superior Court of New Jersey. The Complaint alleges that the defendants named therein, NS, failed to adequately prepare for the commercial launch of the Company's product Deramiocel in the United States pursuant to the U.S. Distribution Agreement, and have otherwise materially breached the terms of the U.S. Distribution Agreement. In the Complaint, the Company sought rescission of the U.S. Distribution Agreement, declaratory judgment that the Company has the right to distribute Deramiocel directly or through distributors other than NS, and other equitable remedies. Capricor subsequently withdrew its application for a preliminary injunction, without prejudice, having determined that resolving this contractual dispute in arbitration following the FDA's decision would give the parties a more complete regulatory record to work from. In the arbitration, NS filed a complaint for Breach of Contract against Capricor and demands declaratory and injunctive relief holding that Capricor breached the Distribution Agreement, that the Distribution Agreement remains in full force and effect, and requiring Capricor to perform its obligations thereunder. Capricor filed counterclaims as follows:

In the arbitration, Capricor counterclaimed for breach of contract (repudiation and failure to perform), breach of the implied covenant of good faith and fair dealing, rescission based on mutual mistake, declaration of Capricor's right to distribute Deramiocel, and unjust enrichment, reserving claims for unilateral mistake and frustration of purpose. Capricor seeks damages for NS's breaches and repudiation, declaratory and injunctive relief holding that the Distribution Agreement

has been repudiated and/or is rescinded such that Capricor is entitled to distribute, or hire another company to distribute, Deramiocel, and in the alternative Capricor seeks restitution for unjust enrichment.

It is difficult to predict the outcome of any dispute, and there can be no assurance that we will prevail in this matter or obtain the remedies we seek. The arbitration process may continue for an extended period of time, may be expensive and time-consuming, and may divert the attention and resources of management and other personnel away from our business operations and strategic objectives. An adverse outcome in the arbitration or in any counterclaims could materially and adversely affect our business, financial condition, results of operations and prospects.

If we are unsuccessful in the arbitration, we may be unable to prevent NS from engaging in activities that we believe are harmful to our business. Any unfavorable ruling could adversely affect our competitive position, reduce potential revenues, impair our ability to commercialize our products, or otherwise negatively impact the market price of our common stock.

Regardless of the outcome, arbitration may generate negative publicity, create uncertainty among customers, distributors, suppliers or collaboration partners, and adversely affect our ability to enter into strategic transactions or obtain financing on favorable terms.

We have a history of net losses, and we expect losses to continue for the foreseeable future. In addition, a number of factors may cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We have a history of net losses, expect to continue to incur substantial net losses for the foreseeable future, and may never achieve or maintain profitability. Our operations to date have been primarily limited to organizing and staffing our company, developing our technology, undertaking preclinical studies and clinical trials of our product candidates, and developing and expanding our manufacturing capabilities for our product candidates. We have not yet obtained regulatory approval for any of our product candidates. Specifically, our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. In particular, our expenditures on the commercialization of Deramiocel, if approved, will heavily depend on the outcome of our dispute with NS and, if we are successful in such dispute, whether we commercialize Deramiocel in the United States directly or through one or more distributors. Other factors relating to our business that may contribute to these fluctuations include the following factors:

- our need for additional capital to fund our trials and development programs;
- delays in the commencement, enrollment, and timing of clinical testing;
- the viability of Deramiocel as a potential product candidate and its development through all stages of clinical development;
- the viability of our exosome technologies as potential product candidates and the advancement of our exosome technologies through all stages of their preclinical and clinical development;
- any delays in regulatory review and approval of our product candidates in clinical development;
- our ability to receive regulatory approval or commercialize our product candidates, within and outside the United States;
- potential side effects of our current or future products and product candidates that could delay or prevent commercialization or cause an approved treatment to be taken off the market;
- market acceptance of our product candidates;
- our ability to establish an effective sales and marketing infrastructure once our products are commercialized, as necessary or to establish partnerships with other companies who have greater sales and marketing capabilities;
- the ability of the Company, Nippon Shinyaku, or another distribution partner, to successfully market and sell our Deramiocel product if and to the extent it is approved;
- our ability to establish or maintain collaborations, licensing or other arrangements, including strategic partnerships for Deramiocel outside of DMD and our exosome technologies;
- our ability and third parties' abilities to obtain and protect intellectual property rights;

- competition from existing products or new products that may emerge;
- guidelines and recommendations of therapies published by various organizations;
- the ability of patients to obtain coverage of, or sufficient reimbursement for, our product candidates;
- our ability to maintain adequate insurance policies;
- our ability to successfully manufacture our product candidates in sufficient quantities and on a timely basis to meet clinical trial and potential commercial demand;
- our dependency on third parties to formulate and manufacture our product candidates, as necessary;
- our ability to maintain and staff our current manufacturing facilities;
- our ability to build or secure new manufacturing facilities, if necessary, and achieve and maintain compliance with current Good Manufacturing Practices and obtain required certifications as required;
- costs related to and outcomes of potential intellectual property litigation, including the recent claim brought against us by Mesoblast;
- compliance with obligations under intellectual property licenses with third parties;
- our ability to implement additional internal systems and infrastructure;
- our ability to adequately support future growth;
- if our products are approved for commercial sale, the ability to secure adequate reimbursement levels for our products;
- our ability to attract and retain key personnel to manage our business effectively; and
- the ability of members of our senior management to manage our business and operations.

If we achieve our near-term product development milestones, we may not be able to manage any subsequent growth.

Should we achieve our near-term product development milestones, of which no assurance can be given, our long-term viability will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources, especially if we expand our business and operations internationally. The extent of our need to expand our operations, particularly with respect to a commercial sales organization, will heavily depend on the outcome of our dispute with NS and, if we are successful in such dispute, whether we commercialize Deramiocel in the United States directly or through one or more distributors. To manage this growth, we will need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel, including people and companies with expertise in commercialization activities, some of whom may be outside consultants who are not our full-time employees. If we are unable to manage our growth effectively, our business would be harmed.

Risks Related to Clinical and Commercialization Activities

We have no experience commercializing and marketing products, and we may be unable to successfully launch, market and sell our products including Deramiocel.

We currently have no FDA approved products and so do not have experience in the commercialization, marketing, sale or distribution of pharmaceutical products on a commercial scale. As a result, even if we are successful in our dispute with NS, we may encounter significant difficulties or delays in successfully launching and commercializing any product candidates for which we obtain regulatory approval.

To successfully commercialize our products, we must develop and implement sales, marketing, market access, distribution, reimbursement and other commercial capabilities, either alone or in collaboration with third parties. We may be unable to effectively recruit, train and retain qualified personnel, establish appropriate distribution relationships, secure adequate reimbursement from government and private payors, or develop sufficient market acceptance among physicians, patients and healthcare providers. In addition, we may face substantial competition from companies with significantly greater commercial infrastructure, financial resources, marketing capabilities and established relationships with customers and payors.

Even if we are able to successfully establish commercial operations, such efforts may be more costly and time-consuming than we anticipate and may not result in meaningful product sales or profitability. We also may encounter operational, logistical, supply chain, customer support and regulatory compliance challenges associated with commercializing products for the first time. If we are unable to successfully commercialize our products, our ability to generate revenue and achieve profitability would be materially adversely affected.

We may also choose to rely on third parties to perform certain commercialization functions, including sales, marketing, distribution and market access activities. Our dependence on third parties may reduce our control over the commercialization process, and such third parties may fail to devote sufficient resources to the marketing and sale of our products or otherwise fail to perform as expected. Any failure to successfully commercialize our products could materially adversely affect our business, financial condition, results of operations and prospects.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate sufficient revenues from sales of drugs to cover our costs and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to alternative therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician and other provider treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration for patients and healthcare practitioners compared to alternative treatments;
- site-of-care requirements, infusion logistics, and the ability of treatment centers and payors to support administration and access on a timely basis;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions and safety information contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- the performance of third-party distributors, if any;
- changes in the standard of care for the targeted indications for the product; and
- the availability of coverage by, and the amount of reimbursement from, government payors, managed care plans and other third-party payors.

We are building commercial capabilities and a corporate compliance program in preparation for the potential launch of Deramiocel, and we may be unable to do so effectively, on a timely basis or at all.

In preparation for the potential approval of Deramiocel, we are building sales, marketing, market access and patient support capabilities, together with a corporate compliance program designed to address the federal Anti-Kickback Statute, the federal civil False Claims Act, the Physician Payments Sunshine Act and analogous state laws that govern the commercial activities of biopharmaceutical companies. We have not previously conducted these activities, and the scope, timing and cost of this effort remain uncertain. Our BLA for Deramiocel remains under FDA review, with a PDUFA target action date of November 22, 2026. In addition, whether we commercialize Deramiocel in the United States directly or through NS or another distributor will depend on the outcome of our arbitration with NS. As a result, we may incur commercial and compliance expenses prematurely or unnecessarily, or we may be unable to complete these capabilities in time to support a timely launch. Although effective compliance programs can mitigate the risk of investigation and

prosecution for violations of healthcare laws, these risks cannot be entirely eliminated. Our compliance program may not prevent our employees, consultants, contractors or distribution partners from engaging in misconduct. Any of these outcomes could materially adversely affect our business.

Risks Related to Our Relationships with Third Parties

We may depend on distributors for the commercial sale of Deramiocel in certain territories, if regulatory approval is obtained.

If we are unsuccessful in our dispute with NS, a substantial portion of our potential revenue for the foreseeable future would depend on milestone, revenue sharing and other payments received from Nippon Shinyaku under our distribution agreements, pursuant to which Nippon Shinyaku has exclusive distribution rights for Deramiocel in the United States and Japan for a significant period of time, with only limited rights of either party to terminate these agreements. In that event, if Nippon Shinyaku failed to successfully commercialize Deramiocel in the United States or Japan, whether due to strategic priorities, financial constraints, insufficient commercial resources, inadequate performance or other factors, our ability to generate revenue from Deramiocel in those territories would be materially limited, which would adversely affect our business, financial condition and results of operations. Even if we are successful in our dispute with NS, we may ultimately partner with one or more distribution partners for the commercialization of Deramiocel in the United States or other territories, and in that event we would depend upon the performance of those distribution partners. The failure of any such distribution partner to successfully commercialize Deramiocel could adversely affect our business, financial condition and results of operations.

If we enter into strategic partnerships, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to terms unfavorable to us.

We are actively looking into potential additional strategic partnerships for our product candidates, particularly for Deramiocel in the United States and additional territories outside the United States and Japan, and for our exosomes product candidates. To the extent that we are successful in our dispute against NS, we may also explore strategic partnerships for the commercialization of Deramiocel in the United States. If we do not establish strategic partnerships, we potentially will have to undertake development and commercialization efforts with respect to our product candidates on our own, which would be costly and adversely impact our ability to commercialize any future products or product candidates. If we enter into any strategic partnerships with pharmaceutical, biotechnology or other life science companies, we will be subject to a number of risks, including:

- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of product candidates;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- strategic partners may not commit adequate resources to necessary pre-launch activities or the marketing and distribution of any future products, limiting our potential revenues from these products;
- disputes may arise between us and our strategic partners, such as our dispute with NS, that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic partner's business strategy may also adversely affect a strategic partner's willingness or ability to complete its obligations under any arrangement; and
- strategic partners could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

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 September 30, 2026, 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) under the Exchange Act 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	Lease Agreement, dated July 9, 2026, between Capricor Therapeutics, Inc. and ARE-SD Region No. 39 Owner, LLC (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 14, 2026).+
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 September 30, 2026 formatted in Inline eXtensible Business Reporting Language (iXBRL): (i) Condensed Consolidated Balance Sheets as of September 30, 2026 and December 31, 2025, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) Condensed Consolidated Statements 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, on November 10, 2026.

CAPRICOR THERAPEUTICS, INC.

Date: November 10, 2026

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

Date: November 10, 2026

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

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Linda Marbán, Ph.D., certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2026

/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: November 10, 2026

/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 September 30, 2026 (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: November 10, 2026

/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 September 30, 2026 (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: November 10, 2026

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