
**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, 2024

or

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from to

Commission File Number: 001-34058

CAPRICOR THERAPEUTICS, INC.
(Exact Name Of Registrant As Specified In Its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

88-0363465
(I.R.S. Employer Identification No.)

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

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

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

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 13, 2024, there were 45,469,908 shares of the registrant's common stock, par value \$0.001 per share, issued and outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- how long we expect to maintain liquidity to fund our planned level of operations and our ability to obtain additional funds for our operations;
- the development of our drug and vaccine candidates, including when we expect to undertake, initiate and complete clinical trials of our drug and vaccine candidates;
- the expectation, plans, projections, initiation, timing, progress and results of our research and development programs, preclinical studies, any clinical trials, compassionate uses, Investigational New Drug filings, Clinical Trial Application filings, New Drug Application filings, Biologics License Application, and other regulatory submissions;
- regulatory developments involving products and our facilities, including the ability to obtain regulatory approvals or otherwise bring products to market;
- the regulatory status of our drug and vaccine candidates, including our ability to obtain and maintain orphan drug, rare pediatric and Regenerative Medicine Advanced Therapy designations for our lead product candidate, deramioceel (also referred to as CAP-1002);
- our ability to obtain approval for our products both in the United States and in countries outside the United States;
- 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;
- our ability to protect our patents and other intellectual property;
- our ability to raise additional financing and the terms of any additional financing;
- our ability to market any of our products;
- the implementation of our business model and strategic plans for our business, technologies and product candidates;
- our estimates of our expenses, ongoing losses, future revenue, future reimbursement prices for any commercial products, and capital requirements;
- the impact of taxes on our business;
- our ability to compete against other companies and research institutions;
- our ability to expand our operations internationally;
- the effect of potential strategic transactions on our business;
- acceptance of our products by doctors, patients or payors and the availability of reimbursement for our product candidates;
- our ability to attract and retain key personnel; and
- the volatility of our stock price.

We caution you that the forward-looking statements highlighted above do not encompass all of the forward-looking statements made in this Quarterly Report on Form 10-Q.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Quarterly Report on Form 10-Q primarily on our current expectations and projections

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about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors. Moreover, we operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Quarterly Report on Form 10-Q. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements. Additionally, final data may differ significantly from preliminary data reported in this document.

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

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

Item 1. Financial Statements.**PART I — FINANCIAL INFORMATION**
CAPRICOR THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

ASSETS

	<u>September 30, 2024</u> <u>(unaudited)</u>	<u>December 31, 2023</u>
CURRENT ASSETS		
Cash and cash equivalents	\$ 68,377,402	\$ 14,694,857
Marketable securities	16,651,222	24,792,846
Receivables	409,682	10,371,993
Prepaid expenses and other current assets	385,065	995,776
TOTAL CURRENT ASSETS	85,823,371	50,855,472
PROPERTY AND EQUIPMENT, net	5,315,385	5,560,641
OTHER ASSETS		
Lease right-of-use assets, net	1,493,611	2,050,042
Other assets	319,246	268,172
TOTAL ASSETS	\$ 92,951,613	\$ 58,734,327
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 6,531,363	\$ 6,250,241
Lease liabilities, current	813,634	749,112
Deferred revenue, current	13,130,509	24,270,465
TOTAL CURRENT LIABILITIES	20,475,506	31,269,818
LONG-TERM LIABILITIES		
CIRM liability	3,376,259	3,376,259
Lease liabilities, net of current	834,889	1,486,783
TOTAL LONG-TERM LIABILITIES	4,211,148	4,863,042
TOTAL LIABILITIES	24,686,654	36,132,860
COMMITMENTS AND CONTINGENCIES (NOTE 6)		
STOCKHOLDERS' EQUITY		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none issued and outstanding	—	—
Common stock, \$0.001 par value, 100,000,000 and 50,000,000 shares authorized, 40,332,392 and 31,148,320 shares issued and outstanding, respectively	40,332	31,148
Additional paid-in capital	260,846,342	181,701,859
Accumulated other comprehensive income	96,221	235,813
Accumulated deficit	(192,717,936)	(159,367,353)
TOTAL STOCKHOLDERS' EQUITY	68,264,959	22,601,467
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 92,951,613	\$ 58,734,327

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
REVENUE				
Revenue	\$ 2,261,642	\$ 6,185,814	\$ 11,139,956	\$ 13,089,977
TOTAL REVENUE	2,261,642	6,185,814	11,139,956	13,089,977
OPERATING EXPENSES				
Research and development	11,807,867	10,028,964	35,413,649	26,507,872
General and administrative	3,463,655	3,021,450	10,593,308	9,378,672
TOTAL OPERATING EXPENSES	15,271,522	13,050,414	46,006,957	35,886,544
LOSS FROM OPERATIONS	(13,009,880)	(6,864,600)	(34,867,001)	(22,796,567)
OTHER INCOME (EXPENSE)				
Investment income	453,152	479,380	1,516,418	1,276,502
Loss on disposal of fixed assets	—	(5,388)	—	(5,388)
TOTAL OTHER INCOME (EXPENSE)	453,152	473,992	1,516,418	1,271,114
NET LOSS	(12,556,728)	(6,390,608)	(33,350,583)	(21,525,453)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	(58,766)	(66,485)	(139,592)	7,964
COMPREHENSIVE LOSS	\$ (12,615,494)	\$ (6,457,093)	\$ (33,490,175)	\$ (21,517,489)
Net loss per share, basic and diluted	\$ (0.38)	\$ (0.25)	\$ (1.04)	\$ (0.85)
Weighted average number of shares, basic and diluted	33,090,063	25,817,676	32,099,181	25,468,880

See accompanying notes to the unaudited condensed consolidated financial statements.

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

	COMMON STOCK		ADDITIONAL PAID- IN CAPITAL	OTHER COMPREHENSIVE INCOME	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance at December 31, 2023	31,148,320	\$ 31,148	\$ 181,701,859	\$ 235,813	\$ (159,367,353)	\$ 22,601,467
Issuance of common stock, net of fees	447,221	447	2,289,797	—	—	2,290,244
Stock-based compensation	—	—	3,265,412	—	—	3,265,412
Stock options exercised	4,642	5	(5)	—	—	—
Unrealized gain on marketable securities	—	—	—	71,888	—	71,888
Net loss	—	—	—	—	(9,794,073)	(9,794,073)
Balance at March 31, 2024	<u>31,600,183</u>	<u>\$ 31,600</u>	<u>\$ 187,257,063</u>	<u>\$ 307,701</u>	<u>\$ (169,161,426)</u>	<u>\$ 18,434,938</u>
Issuance of common stock, net of fees	330,458	331	1,985,518	—	—	1,985,849
Stock-based compensation	—	—	2,152,793	—	—	2,152,793
Stock options exercised	53,286	53	81,169	—	—	81,222
Unrealized loss on marketable securities	—	—	—	(152,714)	—	(152,714)
Net loss	—	—	—	—	(10,999,782)	(10,999,782)
Balance at June 30, 2024	<u>31,983,927</u>	<u>\$ 31,984</u>	<u>\$ 191,476,543</u>	<u>\$ 154,987</u>	<u>\$ (180,161,208)</u>	<u>\$ 11,502,306</u>
Issuance of common stock, net of fees	8,272,427	8,272	67,197,597	—	—	67,205,869
Exercise of common warrants	38,000	38	58,151	—	—	58,189
Stock-based compensation	—	—	2,051,283	—	—	2,051,283
Stock options exercised	38,038	38	62,768	—	—	62,806
Unrealized loss on marketable securities	—	—	—	(58,766)	—	(58,766)
Net loss	—	—	—	—	(12,556,728)	(12,556,728)
Balance at September 30, 2024	<u>40,332,392</u>	<u>\$ 40,332</u>	<u>\$ 260,846,342</u>	<u>\$ 96,221</u>	<u>\$ (192,717,936)</u>	<u>\$ 68,264,959</u>

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	COMMON STOCK		ADDITIONAL PAID-	OTHER	ACCUMULATED	TOTAL
	SHARES	AMOUNT	IN CAPITAL	COMPREHENSIVE	DEFICIT	STOCKHOLDERS'
				INCOME		EQUITY
Balance at December 31, 2022	25,241,402	\$ 25,241	\$ 148,735,420	\$ 105,244	\$ (137,079,811)	\$ 11,786,094
Stock-based compensation	—	—	2,194,784	—	—	2,194,784
Stock options exercised	13,752	14	3,881	—	—	3,895
Unrealized loss on marketable securities	—	—	—	(10,258)	—	(10,258)
Net loss	—	—	—	—	(7,768,266)	(7,768,266)
Balance at March 31, 2023	<u>25,255,154</u>	<u>\$ 25,255</u>	<u>\$ 150,934,085</u>	<u>\$ 94,986</u>	<u>\$ (144,848,077)</u>	<u>\$ 6,206,249</u>
Issuance of common stock, net of fees	452,385	452	2,129,943	—	—	2,130,395
Stock-based compensation	—	—	1,618,712	—	—	1,618,712
Stock options exercised	56,773	57	57,622	—	—	57,679
Unrealized gain on marketable securities	—	—	—	84,707	—	84,707
Net loss	—	—	—	—	(7,366,579)	(7,366,579)
Balance at June 30, 2023	<u>25,764,312</u>	<u>\$ 25,764</u>	<u>\$ 154,740,362</u>	<u>\$ 179,693</u>	<u>\$ (152,214,656)</u>	<u>\$ 2,731,163</u>
Issuance of common stock, net of fees	69,985	70	221,011	—	—	221,081
Stock-based compensation	—	—	1,717,193	—	—	1,717,193
Stock options exercised	20,773	21	(21)	—	—	—
Unrealized loss on marketable securities	—	—	—	(66,485)	—	(66,485)
Net loss	—	—	—	—	(6,390,608)	(6,390,608)
Balance at September 30, 2023	<u>25,855,070</u>	<u>\$ 25,855</u>	<u>\$ 156,678,545</u>	<u>\$ 113,208</u>	<u>\$ (158,605,264)</u>	<u>\$ (1,787,656)</u>

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,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (33,350,583)	\$ (21,525,453)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	—	5,388
Depreciation and amortization	1,049,509	761,274
Stock-based compensation	7,469,488	5,530,689
Changes in lease liabilities	(30,941)	(13,921)
Changes in operating assets and liabilities:		
Receivables	9,962,311	—
Prepaid expenses and other current assets	610,711	461,475
Other assets	(51,074)	—
Accounts payable and accrued expenses	281,122	1,868,032
Deferred revenue	(11,139,956)	(1,089,977)
Net cash used in operating activities	<u>(25,199,413)</u>	<u>(14,002,493)</u>
Cash flows from investing activities:		
Purchase of marketable securities	(69,077,305)	(72,665,821)
Proceeds from sales and maturities of marketable securities	77,079,337	84,955,000
Purchases of property and equipment	(678,073)	(753,056)
Payments for leasehold improvements	(126,180)	(565,255)
Net cash provided by investing activities	<u>7,197,779</u>	<u>10,970,868</u>
Cash flows from financing activities:		
Net proceeds from sale of common stock	71,481,962	2,351,476
Proceeds from exercise of stock awards and warrants	202,217	61,574
Net cash provided by financing activities	<u>71,684,179</u>	<u>2,413,050</u>
Net increase (decrease) in cash and cash equivalents	53,682,545	(618,575)
Cash and cash equivalents balance at beginning of period	14,694,857	9,603,242
Cash and cash equivalents balance at end of period	<u>\$ 68,377,402</u>	<u>\$ 8,984,667</u>
Supplemental disclosures of cash flow information:		
Interest paid in cash	<u>\$ —</u>	<u>\$ —</u>
Income taxes paid in cash	<u>\$ —</u>	<u>\$ —</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

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

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Capricor Therapeutics, Inc., a Delaware corporation (together with its wholly-owned subsidiary, referred to herein as “Capricor Therapeutics,” the “Company,” “we,” “us” or “our”), is a clinical-stage biotechnology company focused on the development of transformative cell and exosome-based therapeutics for treating Duchenne muscular dystrophy (“DMD”), a rare form of muscular dystrophy which results in muscle degeneration and premature death, and other diseases with high unmet medical needs. Capricor, Inc. (“Capricor”), a wholly-owned subsidiary of Capricor Therapeutics, was founded in 2005 as a Delaware corporation. Capricor became public after the completion of a merger between Capricor and a subsidiary of Nile Therapeutics, Inc., a Delaware corporation (“Nile”), in 2013, where Capricor became a wholly-owned subsidiary of Nile and Nile formally changed its name to Capricor Therapeutics, Inc. Capricor Therapeutics was listed on the Nasdaq Capital Market shortly thereafter. Capricor Therapeutics, together with its subsidiary, Capricor, has multiple therapeutic drug candidates in various stages of development.

Basis of Presentation

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

Basis of Consolidation

Our condensed consolidated financial statements include the accounts of the Company and our wholly-owned subsidiary. All intercompany transactions have been eliminated in consolidation.

Reclassification

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

Liquidity and Capital Resources

The Company has an accumulated deficit of approximately \$192.7 million and cash, cash equivalents and marketable securities of approximately \$85.0 million as of September 30, 2024. The Company has historically financed its research and development activities as well as operational expenses primarily from equity financings, government grants, and payments from distribution agreements and collaboration partners. The Company’s principal uses of cash are for research and development expenses, expenses in development of manufacturing capabilities, general and administrative expenses, capital expenditures and other working capital requirements.

On June 21, 2021, the Company established an “at-the-market” program (the “ATM Program”) with an aggregate offering price of up to \$75.0 million, pursuant to a Common Stock Sales Agreement with Wainwright. From June 21, 2021 through October 1, 2024, the Company sold an aggregate of 9,228,383 shares of common stock under the ATM Program at an average price of approximately \$8.13 per share for gross proceeds of approximately \$75.0 million which represents

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all amounts that were available to be sold under the ATM Program (see Note 2 - "Stockholder's Equity"). Effective October 1, 2024, the ATM Program has been closed and terminated.

In the first quarter of 2024, the Company received our first milestone payment of \$10.0 million from Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku"), which was triggered upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile.

In September 2024, the Company completed a private placement with Nippon Shinyaku whereby we issued and sold an aggregate of 2,798,507 shares of common stock at a price per share of \$5.36 for an aggregate purchase price of \$15.0 million (see Note 2 – "Stockholder's Equity").

Subsequent to September 30, 2024, the Company completed an underwritten public offering, pursuant to which the Company issued and sold an aggregate of 5,073,800 shares of common stock at a public offering price of \$17.00 per share for gross proceeds of approximately \$86.3 million (see Note 9 - "Subsequent Events").

The Company's future expenditures and capital requirements may be substantial and will depend on many factors, including, but not limited to, the following:

- the timing and costs associated with our research and development activities, clinical trials and preclinical studies, including the enrollment and progress of our ongoing HOPE-3 Phase 3 clinical trial of deramiocel (also referred to as CAP-1002) in DMD;
- the timing and costs associated with the manufacturing of our product candidates, including the expansion of our manufacturing capacity to support the potential commercialization of deramiocel for DMD;
- the timing and costs associated with potential commercialization of our product candidates;
- the number and scope of our research programs, including the expansion of our exosomes program;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs associated with pursuing marketing approval and potential commercialization of deramiocel in countries outside the United States.

The Company's options for raising additional capital include potentially seeking additional financing primarily from, but not limited to, the sale and issuance of equity or debt securities, the licensing or sale of its technology and other assets, potential distribution and other partnering opportunities, and from government grants. The Company has incurred significant operating losses and negative cash flows from operations. The Company's plan to address its financial position may include potentially seeking additional financing primarily from, but not limited to, the sale and issuance of equity or debt securities, the licensing or sale of its technology and from government grants.

The Company will require substantial additional capital to fund its operations. The Company cannot provide assurances that financing will be available when and as needed or that, if available, financing will be available on favorable or acceptable terms. If the Company is unable to obtain additional financing when and if required, it would have a material adverse effect on the Company's business and results of operations. The Company would likely need to delay, curtail or terminate portions of its clinical trials and research and development programs. To the extent the Company issues additional equity securities, its existing stockholders would experience substantial dilution.

Business Uncertainty Related to the Coronavirus

In light of past uncertainties due to COVID-19 and its economic and other impacts and to uncertainties around the timing and availability of grant disbursements, the loss of revenue from the REGRESS and ALPHA trials as well as any potential equity and debt financings, the Company submitted for the Employee Retention Credit ("ERC"), a credit against certain payroll taxes allowed to an eligible employer for qualifying wages, which was established by the CARES Act. The Company has submitted \$738,778 in ERC for applicable 2020 and 2021 periods, receiving \$191,199 in 2021 and \$191,463 in 2023. As of September 30, 2024, the Company has recorded a receivable for \$366,551 for the remainder of funds for which we are still awaiting receipt.

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Use of Estimates

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

Cash and Cash Equivalents

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

Marketable Securities

The Company determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company's marketable securities are considered as available-for-sale and carried at estimated fair values. Realized gains and losses on the sale of debt and equity securities are determined using the specific identification method. Unrealized gains and losses on available-for-sale securities are presented as accumulated other comprehensive income (loss) as a separate component of stockholders' equity. As of September 30, 2024, marketable securities consist primarily of short-term United States treasuries.

Property and Equipment

Property and equipment are stated at cost. Repairs and maintenance costs are expensed in the period incurred. Depreciation is computed using the straight-line method over the related estimated useful life of the asset, which such estimated useful lives range from five to seven years. Leasehold improvements are depreciated on a straight-line basis over the shorter of the useful life of the asset or the lease term. Depreciation was \$361,167 and \$276,471 for the three months ended September 30, 2024 and 2023, respectively, and \$1,049,509 and \$761,274 for the nine months ended September 30, 2024 and 2023, respectively.

Property and equipment, net consisted of the following:

	September 30, 2024	December 31, 2023
Furniture and fixtures	\$ 197,141	\$ 187,997
Laboratory equipment	6,102,784	5,449,597
Leasehold improvements	2,255,283	2,129,102
	8,555,208	7,766,696
Less accumulated depreciation	(3,239,823)	(2,206,055)
Property and equipment, net	<u>\$ 5,315,385</u>	<u>\$ 5,560,641</u>

Leases

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

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

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

The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

For real estate leases, the Company has elected the practical expedient under ASC 842 to account for the lease and non-lease components together for existing classes of underlying assets and allocates the contract consideration to the lease component only. This practical expedient is not elected for manufacturing facilities and equipment embedded in product supply arrangements.

Revenue Recognition

The Company adopted ASU 606, *Revenue for Contracts from Customers*, (“ASU 606”), which amended revenue recognition principles under U.S. GAAP and provides a single, comprehensive set of criteria for revenue recognition within and across all industries (see Note 7 – “License and Distribution Agreements”).

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

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

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

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

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

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

Grant Income

Generally, government research grants that provide funding for research and development activities are recognized as income when the related expenses are incurred, as applicable. Because the terms of the grant award (the "CIRM Award") from the California Institute for Regenerative Medicine ("CIRM") allow Capricor to elect to convert the grant into a loan after the end of the project period, the CIRM Award is being classified as a liability rather than income (see Note 5 - "Government Grant Awards"). Grant income is due upon submission of a reimbursement request. The transaction price varies for grant income based on the expenses incurred under the awards. No grant income was recognized for the three and nine months ended September 30, 2024 and 2023.

Research and Development

Costs relating to the design and development of new products are expensed as research and development as incurred in accordance with Financial Accounting Standards Board ("FASB") ASC 730-10, *Research and Development*. Research and development costs amounted to approximately \$11.8 million and \$10.0 million for the three months ended September 30, 2024 and 2023, respectively, and approximately \$35.4 million and \$26.5 million for the nine months ended September 30, 2024 and 2023, respectively.

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders' equity during the period except those resulting from investments by, or distributions to, stockholders. The Company's comprehensive loss was approximately \$12.6 million and \$6.5 million for the three months ended September 30, 2024 and 2023, respectively, and approximately \$33.5 million and \$21.5 million for the nine months ended September 30, 2024 and 2023, respectively. The

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Company's other comprehensive income (loss) is related to a net unrealized gain (loss) on marketable securities. The Company's other comprehensive income (loss) was \$(58,766) and \$(66,485) for the three months ended September 30, 2024 and 2023, respectively, and \$(139,592) and \$7,964 for the nine months ended September 30, 2024 and 2023, respectively.

Clinical Trial Expense

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

Stock-Based Compensation

The Company accounts for stock-based employee compensation arrangements in accordance with guidance issued by the FASB, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, consultants, and directors based on estimated fair values.

The Company estimates the fair value of stock-based compensation awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the Company's statements of operations and comprehensive loss. The Company estimates the fair value of stock-based compensation awards using the Black-Scholes model. This model requires the Company to estimate the expected volatility and value of its common stock and the expected term of the stock options, all of which are highly complex and subjective variables. The variables take into consideration, among other things, actual and projected stock option exercise behavior. For employees and directors, the expected life was calculated based on the simplified method as described by the SEC Staff Accounting Bulletin No. 110, Share-Based Payment. For other service providers, the expected life was calculated using the contractual term of the award. The Company's estimate of expected volatility was based on the historical stock price of the Company. The Company has selected a risk-free rate based on the implied yield available on U.S. Treasury securities with a maturity equivalent to the expected term of the options.

Basic and Diluted Loss per Share

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

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For the three and nine months ended September 30, 2024 and 2023, warrants and options to purchase 15,454,599 and 8,303,253 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, 2024 and 2023.

Fair Value Measurements

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

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

The following table summarizes the fair value measurements by level at September 30, 2024 and December 31, 2023 for assets and liabilities measured at fair value on a recurring basis:

	September 30, 2024			
	Level I	Level II	Level III	Total
Marketable Securities	\$ 16,651,222	\$ —	\$ —	\$ 16,651,222

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

Carrying amounts reported in the balance sheet of cash and cash equivalents, receivables, accounts payable and accrued expenses approximate fair value due to their relatively short maturity. The carrying amounts of the Company's marketable securities are based on market quotations from national exchanges at the balance sheet date. Interest and dividend income are recognized separately on the income statement based on classifications provided by the brokerage firm holding the investments. The fair value of borrowings is not considered to be significantly different from its carrying amount because the stated rates for such debt reflect current market rates and conditions.

Recent Accounting Pronouncements

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

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the SEC, did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statement presentation or disclosures.

2. STOCKHOLDER'S EQUITY

September 2024 Private Placement

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

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

ATM Program

The Company established an ATM Program on June 21, 2021, with an aggregate offering price of up to \$75.0 million, pursuant to a Common Stock Sales Agreement with Wainwright by which Wainwright sold our common stock at the market prices prevailing at the time of sale. Wainwright is entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold plus reimbursement of certain expenses.

From June 21, 2021 through October 1, 2024, the Company sold an aggregate of 9,228,383 shares of common stock under the ATM Program at an average price of approximately \$8.13 per share for gross proceeds of approximately \$75.0 million which represents all amounts that were available to be sold under the ATM Program. Effective October 1, 2024, the ATM Program was closed and terminated. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to Wainwright, as well as legal and accounting fees in the aggregate amount of approximately \$2.4 million.

September 2023 Financing

On September 29, 2023, the Company entered into Securities Purchase Agreements, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "Registered Direct Offering"), an aggregate of 4,935,621 shares of its common stock, par value \$0.001 per share, at a price per share of \$4.66 for an aggregate purchase price of approximately \$23.0 million. Each share of common stock offered was sold with a warrant to purchase one share of common stock at an exercise price of \$5.70 per share. Each warrant became exercisable beginning six months after issuance and will expire seven years from the date of issuance.

Outstanding Shares

At September 30, 2024, the Company had 40,332,392 shares of common stock issued and outstanding.

3. STOCK AWARDS, WARRANTS AND OPTIONS

Warrants

The following table summarizes all warrant activity for the nine months ended September 30, 2024:

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2023	5,041,403	\$ 5.61
Granted	—	—
Exercised	(38,000)	1.53
Outstanding at September 30, 2024	<u>5,003,403</u>	<u>\$ 5.64</u>

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

Type	Grant Date	Warrants Outstanding		Exercise Price per Share	Expiration Date
		September 30, 2024	December 31, 2023		
Common Warrants	12/19/2019	40,782	40,782	\$ 1.10	12/19/2024
Common Warrants	3/27/2020	27,000	65,000	\$ 1.5313	3/27/2025
Common Warrants	10/3/2023	4,935,621	4,935,621	\$ 5.70	10/3/2030
		<u>5,003,403</u>	<u>5,041,403</u>		

Stock Options

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

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

As of September 30, 2024, 458,869 options remain available for issuance under the respective stock option plans.

The Company's stock option plans are administered by the Board, in conjunction with the compensation committee of the Board, which determines the recipients and types of awards to be granted, as well as the number of shares subject to the awards, the exercise price and the vesting schedule. Each stock option granted will be designated in the award agreement as either an incentive stock option or a nonstatutory stock option. Notwithstanding such designation, however, to the extent that the aggregate fair market value of the shares with respect to which incentive stock options are exercisable for the first time by the participant during any calendar year (under all plans of the Company and any parent or subsidiary) exceeds \$100,000, such options will be treated as nonstatutory stock options. Stock options are granted with an exercise price not less than equal to the closing price of the Company's common stock on the date of grant, and generally vest over a period of one to four years. The term of stock options granted under each of the plans cannot exceed ten years.

The estimated weighted average fair value of the options granted during the three months ended September 30, 2024 and 2023 were approximately \$4.16 and \$4.93 per share, respectively. The estimated weighted average fair value of

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the options granted during the nine months ended September 30, 2024 and 2023 were approximately \$4.56 and \$3.88 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, 2024 and 2023:

	Nine months ended September 30,	
	2024	2023
Expected volatility	109 - 119 %	111 - 121 %
Expected term	5 - 7 years	5 - 7 years
Dividend yield	0 %	0 %
Risk-free interest rates	3.9 - 4.5 %	3.5 - 4.5 %

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

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
General and administrative	\$ 1,274,238	\$ 1,235,219	\$ 4,852,244	\$ 4,157,704
Research and development	777,045	481,974	2,617,244	1,372,985
Total	\$ 2,051,283	\$ 1,717,193	\$ 7,469,488	\$ 5,530,689

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

Common stock, stock options or other equity instruments issued to non-employees (including consultants) as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued. The fair value of stock options is determined using the Black-Scholes option-pricing model. The Company calculates the fair value for non-qualified options as of the date of grant and expenses over the applicable vesting periods. The Company accounts for forfeitures upon occurrence.

As of September 30, 2024, the total unrecognized fair value compensation cost related to non-vested stock options was approximately \$16.6 million, which is expected to be recognized over a weighted average period of approximately 1.4 years.

The following is a schedule summarizing employee and non-employee stock option activity for the nine months ended September 30, 2024:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2023	8,232,404	\$ 3.46	
Granted	2,732,226	5.25	
Exercised	(107,073)	1.98	\$ 305,501
Expired/Cancelled	(406,361)	5.33	
Outstanding at September 30, 2024	10,451,196	\$ 3.87	\$ 118,501,497
Exercisable at September 30, 2024	6,118,062	\$ 3.36	\$ 72,516,118

The aggregate intrinsic value represents the difference between the exercise price of the options and the estimated fair value of the Company's common stock for each of the respective periods.

4. CONCENTRATIONS

Concentration of Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash, cash equivalents, and marketable securities. The Company maintains accounts at three financial institutions. These accounts are insured by the Federal Deposit Insurance Corporation (the “FDIC”) for up to \$250,000 and/or the Securities Investor Protection Corporation, as applicable. The Company’s cash, cash equivalents, and marketable securities in excess of the FDIC insured limits as of September 30, 2024, were approximately \$85.0 million. The Company monitors the financial stability of the financial institutions with which it maintains accounts and believes it is not exposed to any significant credit risk in cash and cash equivalents. Historically, the Company has not experienced any significant losses in such accounts and does not believe it is exposed to any significant credit risk due to the quality nature of the financial instruments in which the money is held.

5. GOVERNMENT GRANT AWARDS

CIRM Grant Award (HOPE)

On June 16, 2016, Capricor entered into the CIRM Award with CIRM in the amount of approximately \$3.4 million to fund, in part, Capricor’s Phase I/II HOPE-Duchenne clinical trial investigating deramiocel for the treatment of DMD-associated cardiomyopathy. Pursuant to terms of the CIRM Award, the disbursements were tied to the achievement of specified operational milestones. In addition, the terms of the CIRM Award included a co-funding requirement pursuant to which Capricor was required to spend approximately \$2.3 million of its own capital to fund the CIRM funded research project. The CIRM Award is further subject to the conditions and requirements set forth in the CIRM Grants Administration Policy for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, California Code of Regulations (CCR) Sections 100600-100612, and the sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from the CIRM funded research as set forth in Title 17, CCR Section 100608. The maximum royalty on net commercial revenue that Capricor may be required to pay to CIRM is equal to nine times the total amount awarded and paid to Capricor.

After completing the CIRM funded research project and at any time after the award period end date (but no later than the ten-year anniversary of the date of the award), Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and development of the program at the time the election is made. On June 20, 2016, Capricor entered into a Loan Election Agreement with CIRM whereby, among other things, CIRM and Capricor agreed that if Capricor elects to convert the grant into a loan, the term of the loan could be up to five years from the date of execution of the applicable loan agreement; provided that the maturity date of the loan will not surpass the ten-year anniversary of the grant date of the CIRM Award. Beginning on the date of the loan, the loan shall bear interest on the unpaid principal balance, plus the interest that has accrued prior to the election point according to the terms set forth in the CIRM Loan Policy and CIRM Grants Administration Policy for Clinical Stage Projects (the “New Loan Balance”), at a per annum rate equal to the LIBOR rate for a three-month deposit in U.S. dollars, as published by the Wall Street Journal on the loan date, plus one percent. Interest shall be compounded annually on the outstanding New Loan Balance commencing with the loan date and the interest shall be payable, together with the New Loan Balance, upon the due date of the loan. If Capricor elects to convert the CIRM Award into a loan, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements. Capricor has not yet made its decision as to whether it will elect to convert the CIRM Award into a loan. Depending on the timing of our election, additional funds may be owed. If we elect to do so, Capricor would be required to repay the amounts awarded by CIRM; therefore, the Company accounts for this award as a liability rather than income.

In 2019, Capricor completed all milestones and close-out activities associated with the CIRM Award and expended all funds received. As of September 30, 2024, Capricor’s liability balance for the CIRM Award was approximately \$3.4 million.

6. COMMITMENTS AND CONTINGENCIES

Short-Term Operating Leases

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

Commencing March 13, 2024, we entered into a License and Services Agreement with Azzur Cleanrooms-on-Demand – San Diego, LLC (the "Azzur License Agreement") pursuant to which we were granted an exclusive license to use certain space and the non-exclusive right to use certain equipment and property for our early phase clinical and/or pre-clinical manufacturing purposes. Our license fee was approximately \$110,615 per month. The initial license agreement term expired on September 26, 2024, which the Company extended through November 8, 2024. At this time, we are evaluating the opportunity to potentially enter into a short-term lease for the premises.

Expenses incurred under short-term operating leases for the three months ended September 30, 2024 and 2023 were \$339,954 and \$22,857, respectively, and \$787,571 and \$70,071 for the nine months ended September 30, 2024 and 2023, respectively. Short-term operating lease payments for the three months ended September 30, 2024 and 2023 were \$22,857 and \$22,857, respectively, and \$787,571 and \$70,071 for the nine months ended September 30, 2024 and 2023, respectively.

Long-Term Operating Leases

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

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

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

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

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The tables below exclude short-term operating leases. The following table summarizes maturities of lease liabilities and the reconciliation of lease liabilities as of September 30, 2024:

2024 (remainder)	\$	226,677
2025		914,220
2026		634,889
2027		—
2028		—
Total minimum lease payments		1,775,786
Less: imputed interest		(127,263)
Total operating lease liabilities	\$	1,648,523
Included in the condensed consolidated balance sheet:		
Current portion of lease liabilities	\$	813,634
Lease liabilities, net of current		834,889
Total operating lease liabilities	\$	1,648,523
Other Information:		
Weighted average remaining lease term		1.9 years
Weighted average discount rate		7.4%

As of September 30, 2024, ROU assets for operating leases were approximately \$1.5 million and operating lease liabilities were approximately \$1.6 million. The following table contains a summary of the lease costs recognized and lease payments pertaining to the Company's long-term operating leases under ASC 842 for the period indicated.

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Lease costs	\$ 210,357	\$ 198,041	\$ 631,072	\$ 583,253
Lease payments	221,099	199,058	676,921	597,173

Legal Contingencies

The Company is not a party to any material legal proceedings at this time. From time to time, the Company may become involved in various legal proceedings that arise in the ordinary course of its business or otherwise. The Company records a loss contingency reserve for a legal proceeding when it considers the potential loss probable and it can reasonably estimate the amount of the loss or determine a probable range of loss. The Company has not recorded any material accruals for loss contingencies as of September 30, 2024.

Accounts Payable

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

Other Funding Commitments

The Company is a party to various agreements, principally relating to licensed technology, that require future payments relating to milestones that may be met in subsequent periods or royalties on future sales of specific products (see Note 7 – "License and Distribution Agreements").

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

Employee Severances

The Board of Directors from time to time may approve severance packages for specific full-time employees based on their length of service and position ranging up to six months of their base salaries, in the event of termination of their employment, subject to certain conditions. No liability under these severance packages has been recorded as of September 30, 2024.

7. LICENSE AND DISTRIBUTION AGREEMENTS

Intellectual Property Rights for Capricor's Technology - CAP 1002 and Exosomes

Capricor has entered into exclusive license agreements for intellectual property rights related to certain cardiac-derived cells with Università Degli Studi Di Roma La Sapienza (the "University of Rome"), Johns Hopkins University ("JHU") and CSMC. Capricor has also entered into an exclusive license agreement for intellectual property rights related to exosomes with CSMC. In addition, Capricor has filed patent applications related to the technology developed by its own scientists.

University of Rome License Agreement

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

Pursuant to the Rome License Agreement, Capricor paid the University of Rome a license issue fee, is currently paying minimum annual royalties in the amount of 20,000 Euros per year, and is obligated to pay a lower-end of a mid-range double-digit percentage on all royalties received as a result of sublicenses granted, which are net of any royalties paid to third parties under a license agreement from such third party to Capricor. The minimum annual royalties are creditable against future royalty payments.

The Rome License Agreement will, unless extended or sooner terminated, remain in effect until the later of the last claim of any patent or until any patent application comprising licensed patent rights has expired or been abandoned. Under the terms of the Rome License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy. Either party may terminate the agreement upon the other party's material breach, provided that the breaching party will have up to 90 days to cure its material breach. Capricor may also terminate for any reason upon 90 days' written notice to the University of Rome.

The Johns Hopkins University License Agreements

License Agreement for CDCs

Capricor and JHU entered into an Exclusive License Agreement, effective June 22, 2006 (the "JHU License Agreement"), which provides for the grant of an exclusive, world-wide, royalty-bearing license by JHU to Capricor (with the right to sublicense) to develop and commercialize licensed products and licensed services under the licensed patent rights in all fields and a nonexclusive right to the know-how. Various amendments were entered into to revise certain provisions of the JHU License Agreement. Under the JHU License Agreement, Capricor is required to exercise commercially reasonable and diligent efforts to develop and commercialize licensed products covered by the licenses from JHU.

Pursuant to the JHU License Agreement, JHU was paid an initial license fee and, thereafter, Capricor is required to pay minimum annual royalties on the anniversary dates of the JHU License Agreement. The minimum annual royalties are creditable against a low single-digit running royalty on net sales of products and net service revenues, which Capricor is also required to pay under the JHU License Agreement, which running royalty may be subject to further reduction in the event that Capricor is required to pay royalties on any patent rights to third parties in order to make or sell a licensed

product. In addition, Capricor is required to pay a low double-digit percentage of the consideration received by it from sublicenses granted and is required to pay JHU certain defined development milestone payments upon the successful completion of certain phases of its clinical studies and upon receiving approval from the U.S. Food and Drug Administration (the “FDA”). The maximum aggregate amount of milestone payments payable under the JHU License Agreement, as amended, is \$1,850,000. In 2022, Capricor paid the \$250,000 development milestone related to the Phase 2 study pursuant to the terms of the JHU License Agreement. The next milestone is triggered upon successful completion of a full Phase 3 study for which a payment of \$500,000 will be due.

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

Cedars-Sinai Medical Center License Agreements

License Agreement for CDCs

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

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

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

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

The Amended CSMC License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Amended CSMC License Agreement, unless waived by CSMC, the agreement shall automatically terminate: (i) if Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) after 90 days’ notice from CSMC if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights, and fails to cure that breach after 90

days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. Capricor may terminate the agreement if CSMC fails to cure any material breach within 90 days after notice.

Capricor and CSMC have entered into several amendments to the Amended CSMC License Agreement, pursuant to which the parties agreed to add and delete certain patent applications from the list of scheduled patents and extend the timing of certain development milestones, among other things. Capricor reimbursed CSMC for certain attorneys' fees and filing fees incurred in connection with the additional patent applications.

License Agreement for Exosomes

On May 5, 2014, Capricor entered into an Exclusive License Agreement with CSMC (the "Exosomes License Agreement"), for certain intellectual property rights related to CDC-derived exosomes technology. The Exosomes License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) in order to conduct research using the patent rights and know-how and to develop and commercialize products in the field using the patent rights and know-how. In addition, Capricor has the exclusive right to negotiate for an exclusive license to any future rights arising from related work conducted by or under the direction of Dr. Eduardo Marbán on behalf of CSMC. In the event the parties fail to agree upon the terms of an exclusive license, Capricor shall have a non-exclusive license to such future rights, subject to royalty obligations.

Pursuant to the Exosomes License Agreement, CSMC was paid a license fee and Capricor reimbursed CSMC for certain fees and costs incurred in connection with the preparation and prosecution of certain patent applications. Additionally, Capricor is required to meet certain non-monetary development milestones and is obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a single-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third party for patent rights in connection with the royalty bearing product.

The Exosomes License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Exosomes License Agreement, unless waived by CSMC, the agreement shall automatically terminate: (i) if Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) after 90 days if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights and fails to cure that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. Capricor may terminate the agreement if CSMC fails to cure any material breach within 90 days after notice.

Capricor and CSMC have entered into several amendments to the Exosomes License Agreement. Collectively, these amendments added additional patent applications and patent families to the Exosomes License Agreement, added certain defined product development milestone payments, modified certain milestone deadlines, added certain performance milestones with respect to product candidates covered by certain future patent rights in order to maintain an exclusive license to those future patent rights, and converted certain exclusive rights to co-exclusive rights. These amendments also obligated Capricor to reimburse CSMC for certain attorneys' fees and filing fees in connection with the additional patent applications and patent families.

Cell Line License Agreement with Life Technologies

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

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

On January 24, 2022, Capricor entered into the U.S. Distribution Agreement with Nippon Shinyaku, a Japanese corporation 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 deramiocecel for the treatment of DMD.

Under the terms of the U.S. Distribution Agreement, Capricor will be responsible for the clinical development and manufacturing of deramiocecel. Nippon Shinyaku and NS Pharma, Inc. (its wholly-owned U.S. subsidiary) will be responsible for the distribution of deramiocecel in the United States. Pursuant to the U.S. Distribution Agreement, Capricor received an upfront payment of \$30.0 million in 2022. The first milestone payment of \$10.0 million was paid upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. Additionally, there are potential milestones totaling up to \$90.0 million leading up to and including the BLA approval. Further, there are various potential sales-based milestones, if commercialized, tied to the achievement of certain sales thresholds for annual net sales of deramiocecel of up to \$605.0 million. Subject to regulatory approval, Capricor will have the right to receive a meaningful mid-range double-digit share of product revenue which falls between 30 and 50 percent.

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

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

For the three months ended September 30, 2024, the Company recognized approximately \$2.3 million as revenue compared to approximately \$6.2 million for the three months ended September 30, 2023. For the nine months ended September 30, 2024, the Company recognized approximately \$11.1 million as revenue compared to approximately \$13.1 million for the nine months ended September 30, 2023. In relation to the U.S. Distribution Agreement, as of September 30, 2024, the Company recorded approximately \$1.1 million as current deferred revenue on the Company’s condensed consolidated balance sheets.

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

The transaction price allocated to remaining performance obligations represents contracted revenue that has not yet been recognized. As of September 30, 2024, remaining performance obligations related to the U.S. Distribution Agreement were approximately \$1.1 million. At this time, we estimate 100% of the remaining performance obligations are expected to be recognized over the next 12 months. Remaining performance obligations estimates are subject to change.

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

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

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

The Company has evaluated the Japan Distribution Agreement in accordance with ASU 606, *Revenue for Contracts from Customers*. The Company determined the initial transaction price totaled \$12.0 million, which was the upfront payment fee. The Company has excluded any future milestone or shared revenue payments from this transaction price to date based on probability. At this time, the Company is evaluating the regulatory pathway to achieve potential product approval in this territory. Until such time, the Company cannot identify any distinct performance obligation. As such, the Company has recorded the entire upfront payment fee of \$12.0 million as current deferred revenue on the Company’s condensed consolidated balance sheets as of September 30, 2024.

Binding Term Sheet with Nippon Shinyaku (Territory: Europe)

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

8. RELATED PARTY TRANSACTIONS

Consulting Agreements

In 2013, Capricor entered into a Consulting Agreement with Dr. Frank Litvack, the Company’s Executive Chairman and a member of its Board of Directors, whereby Capricor agreed to pay Dr. Litvack \$10,000 per month for consulting services. The agreement is terminable upon 30 days’ notice. As of September 30, 2024 and December 31, 2023, \$10,000 was recorded in accounts payable and accrued expenses related to this Consulting Agreement.

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

Commercialization and Distribution Agreements

As noted above, Capricor is party to multiple commercialization and distribution agreements with Nippon Shinyaku, which holds more than 10% of the outstanding capital stock of Capricor Therapeutics (see Note 7 – “License and Distribution Agreements”). There are no outstanding payables or receivables as of September 30, 2024.

9. SUBSEQUENT EVENTS

October 2024 Underwritten Public Offering

On October 16, 2024, the Company entered into an underwriting agreement (the “Underwriting Agreement”) with Piper Sandler and Oppenheimer as representatives of the underwriters (the “Underwriters”), pursuant to which the Company agreed to sell and issue, in a public offering an aggregate of 5,073,800 shares of common stock, including the exercise in full of the underwriters’ option to purchase additional shares to cover over allotments, at a public offering price of \$17.00 per share for total gross proceeds of approximately \$86.3 million, before deducting underwriting commissions and other offering expenses payable by Capricor. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to the Underwriters, as well as legal and accounting fees in the aggregate amount of approximately \$5.5 million.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the condensed consolidated notes to those statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, our actual results may differ materially from those anticipated in these forward-looking statements.

As used in this Quarterly Report on Form 10-Q, references to "Capricor Therapeutics," the "Company," "we," "us," "our" or similar terms include Capricor Therapeutics, Inc. and its wholly-owned subsidiary. References to "Capricor" are with respect to Capricor, Inc., our wholly-owned subsidiary.

Overview

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

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

Our core program is focused on the development and commercialization of a cell therapy technology (referred herein as deramiocel) comprised of cardiosphere-derived cells ("CDCs"), which are a population of stromal cells isolated from donated cells of healthy human hearts, for the treatment of DMD. Deramiocel is designed to slow disease progression in DMD through the immunomodulatory, anti-inflammatory, pro-angiogenic and anti-fibrotic actions of CDCs, which are mediated by secreted exosomes laden with bioactive cargo. Among the cargo elements known to be bioactive in CDC-exosomes are microRNAs. Collectively, these non-coding RNA species alter gene expression in macrophages and other target cells, dialing down generalized inflammation and stimulating tissue regeneration in DMD (and in a variety of other inflammatory diseases). This mechanism of action, consistent with the changes observed in clinical studies to date in circulating inflammatory biomarkers, contrasts with that of exon-skipping oligonucleotides and gene therapy approaches, which aim to restore dystrophin expression. DMD pathophysiology is driven by the impaired production of functional dystrophin which normally functions as a structural protein in muscle. The reduction of functional dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. In DMD patients, heart muscle cells progressively die and are replaced with scar tissue. This cardiomyopathy eventually leads to heart failure, which is currently the leading cause of death among those with DMD. The annual cost of care for patients with DMD is very high and increases with disease progression. There is no currently approved treatment for cardiomyopathy in DMD, therefore, we believe that DMD represents a significant market opportunity for our product candidate, deramiocel.

To date, we have completed multiple promising clinical trials investigating deramiocel for treatment of DMD. The results of our Phase 2, HOPE-2 study were published in The Lancet showing that the trial met its primary efficacy endpoint of the mid-level dimension of the Performance of the Upper Limb ("PUL") v1.2 (p=0.01) and additional positive

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endpoints of full PUL v2.0 ($p=0.04$) and a cardiac endpoint of left ventricular ejection fraction ($p=0.002$). Deramiocel was generally safe and well-tolerated throughout the study.

Additionally, we are currently conducting an open label extension (“OLE”) study of the HOPE-2 trial in which 12 patients have elected to continue treatment of deramiocel. We recently presented three-year data showing a statistically significant benefit (+3.7 points, $p < 0.001$) in the PUL v2.0 total score when compared to an external comparator dataset of similar DMD patients. Data also showed improvements in multiple cardiac measures, including left ventricular ejection fraction, as well as indexed volumes (left ventricular end systolic volume and left ventricular end diastolic volume). Improvements as measured by cardiac MRI were observed at both the 24-month and 36-month timepoints. These are measures of cardiac function and are considered highly relevant in terms of predicting long-term outcomes. Deramiocel treatment during the OLE portion of the study continues to yield a consistent safety profile and has been well-tolerated throughout the study.

In August 2024, we held a pre-BLA meeting with FDA, where we discussed our rolling BLA submission schedule, potential label expansion, plans for commercial manufacturing as well as other topics. Subsequent to this meeting, we held several additional meetings with FDA and announced our intent to file a Biologics License Application (“BLA”) based on existing cardiac data from the Phase 2 HOPE-2 and HOPE-2 OLE trials compared to patient-level natural history data to treat all patients diagnosed with DMD-cardiomyopathy. We initiated the BLA filing in October of 2024 and the full submission is expected to be completed by year end 2024. To support potential label expansion to treat DMD, we plan to provide clinical data on skeletal muscle myopathy by combining Cohorts A and B of the Phase 3 HOPE-3 clinical trial to serve as a post-approval study and do not intend to unblind Cohort A at this time, which was originally planned to occur in the fourth quarter of 2024. Furthermore, if necessary, the HOPE 3 study will also be supporting ex-U.S. marketing authorizations. Currently, we have initiated regulatory activities in Europe and Japan and will be working with the various health authorities to develop the most efficient path for regulatory approval of deramiocel in these regions.

The regulatory pathway for deramiocel in the U.S. is supported by RMAT designation as well as orphan drug designation. In addition, if Capricor were to receive FDA marketing approval for deramiocel for the treatment of DMD, Capricor would be eligible to receive a Priority Review Voucher (“PRV”) based on its previous receipt of a rare pediatric disease designation. Capricor retains full rights to the PRV, if received. Further, Capricor has entered into two Commercialization and Distribution Agreements with Nippon Shinyaku appointing Nippon Shinyaku as its exclusive distributor of deramiocel in the United States and Japan.

We continue to develop our engineered exosome technology using our proprietary StealthX™ platform focused on the areas of targeted therapeutics and vaccines to potentially treat and prevent a diverse array of diseases. Exosomes are membrane-bound extracellular vesicles that contain lipids, proteins and nucleic acids. They act as messengers to regulate the functions of neighboring or distant cells. Their size, low or null immunogenicity and ability to communicate in native cellular language potentially make them an exciting new class of therapeutic agents with the potential to expand our ability to address complex biological responses. Our StealthX™ platform is focused on developing precision-engineered exosomes that have the ability to deliver defined sets of effector molecules that exert their effects through defined mechanisms of action to the defined target. Our platform builds on advances in fundamental RNA and protein science, targeting technology and manufacturing, providing us the opportunity to potentially build a broad pipeline of new therapeutic candidates. At this time, we are developing exosome-based vaccines and therapeutics for infectious diseases, monogenic diseases and other potential indications. Our current strategy is focused on securing partners who will provide capital and additional resources to enable us to bring this program into the clinic.

In the first quarter of 2024, we announced that we have been selected to be part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines providing broader and more durable protection for COVID-19. As part of Project NextGen, the National Institute of Allergy and Infectious Diseases (“NIAID”), part of the National Institutes of Health, will conduct a Phase 1 clinical study with our StealthX™ vaccine, subject to regulatory approval. Currently, our StealthX™ vaccine candidate is in the manufacturing phase with current plans to deliver it to NIAID in the first quarter of 2025. At this time, we are updating the Investigational New Drug Application (“IND”) we have previously submitted to the FDA for our StealthX™ vaccine, so that the NIAID IND can refer to it. Subject to FDA clearance, NIAID plans to initiate this trial in the first quarter of 2025 and we expect to have preliminary data available in the second quarter of 2025, subject to availability from NIAID. Furthermore, if NIAID finds

that our StealthX™ vaccine meets its criteria for safety and efficacy, they may consider funding our program further into a Phase 2 study.

As of September 30, 2024, we had cash, cash equivalents, and marketable securities totaling approximately \$85.0 million. Subsequent to September 30, 2024, the Company completed an underwritten public offering, pursuant to which we issued and sold an aggregate of 5,073,800 shares of common stock for gross proceeds of approximately \$86.3 million. We believe that our existing cash balance will enable us to fund our planned operating expenses and capital expenditure requirements through at least the next 12 months.

We have not generated any revenues from the commercial sale of products. We will not be able to generate any product revenues until, and only if, we receive approval to sell our drug candidates from the FDA or other regulatory authorities. Due to our significant research and development expenditures, and general administrative costs associated with our operations, we have generated substantial operating losses in each period since our inception. Our net losses were approximately \$12.6 million and \$6.4 million for the three months ended September 30, 2024 and 2023, respectively. Our net losses were approximately \$33.4 million and \$21.5 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of approximately \$192.7 million. We expect to incur significant expenses and operating losses for the foreseeable future.

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

Financial Operations Overview

We have no commercial product sales to date and will not have the ability to generate any commercial product revenue until after we have received approval from the FDA or equivalent foreign regulatory bodies to begin selling our product candidates. Developing biological products is a lengthy and very expensive process. Even if we obtain the capital necessary to continue the development of our product candidates, whether through a strategic transaction or otherwise, we do not expect to complete the development of a product candidate for several years, if ever. To date, most of our development expenses have related to our product candidates, consisting of deramiocel and our exosome technologies. As we proceed with the clinical development of deramiocel, and as we further develop our exosome technologies, our expenses will further increase. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development of our products and our clinical programs. Our recent major sources of working capital have been primarily proceeds from public equity sales of securities and upfront payments pursuant to our Distribution Agreements with Nippon Shinyaku. While we pursue our preclinical and clinical programs, we continue to explore potential partnerships for the development of one or more of our product candidates in the US and in other territories across the world.

Our results have included non-cash compensation expense due to the issuance of stock options and warrants, as applicable. We expense the fair value of stock options and warrants over their vesting period as applicable. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based conditions. Stock-based compensation expense is included in the condensed consolidated statements of operations under general and administrative (“G&A”) or research and development (“R&D”) expenses, as applicable. We expect to record additional non-cash compensation expense in the future, which may be significant.

Results of Operations

Revenue

Clinical Development Income. Clinical development income for the three months ended September 30, 2024 and 2023 was approximately \$2.3 million and \$6.2 million, respectively. Clinical development income for the nine months ended September 30, 2024 and 2023 was approximately \$11.1 million and \$13.1 million, respectively. The Company currently recognizes \$40.0 million in payments received from Nippon Shinyaku related to an Exclusive Commercialization and Distribution Agreement (the “U.S. Distribution Agreement”). Revenue is ratably recognized using a proportional performance method in relation to the completion of the HOPE-3 clinical trial (Cohort A).

Operating Expenses

Research and Development Expenses. R&D expenses consist primarily of compensation and other related personnel costs, supplies, clinical trial costs, patient treatment costs, rent for laboratories and manufacturing facilities, consulting fees, costs of personnel and supplies for manufacturing, costs of service providers for preclinical, clinical and manufacturing, certain legal expenses resulting from intellectual property prosecution, stock-based compensation expense and other expenses relating to the design, development, testing and enhancement of our product candidates.

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

	Three months ended September 30,		Change (\$)	Change (%)
	2024	2023		
Compensation and other personnel expenses	\$ 3,684,188	\$ 2,726,092	\$ 958,096	35 %
Duchenne muscular dystrophy program (deramiocel)	5,430,428	5,616,093	(185,665)	(3)%
Exosomes platform research	842,952	549,022	293,930	54 %
Facility expenses	755,373	379,969	375,404	99 %
Stock-based compensation	777,045	481,974	295,071	61 %
Depreciation	200,727	162,794	37,933	23 %
Research and other	117,154	113,020	4,134	4 %
Total research and development expenses	<u>\$ 11,807,867</u>	<u>\$ 10,028,964</u>	<u>\$ 1,778,903</u>	<u>18 %</u>

R&D expenses for the three months ended September 30, 2024 increased by approximately \$1.8 million, or 18%, compared to the three months ended September 30, 2023. The increase was primarily driven by the following:

- \$1.0 million increase in compensation and other personnel expenses primarily due to increases in headcount;
- \$0.3 million increase in research expenses related to our exosomes platform primarily related to our collaboration with NIAID;
- \$0.4 million increase in facility expenses primarily related to expanded leased space; and
- \$0.3 million increase in stock-based compensation expense primarily due to increases in headcount.

The increase was partially offset by an approximate \$0.2 million decrease in DMD (deramiocel) program-related expenses.

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	Nine months ended September 30,		Change (\$)	Change (%)
	2024	2023		
Compensation and other personnel expenses	\$ 10,697,603	\$ 7,419,586	\$ 3,278,017	44 %
Duchenne muscular dystrophy program (deramiocele)	16,674,567	14,325,922	2,348,645	16 %
Exosomes platform research	2,518,052	1,566,963	951,089	61 %
Facility expenses	1,982,886	1,033,799	949,087	92 %
Stock-based compensation	2,617,244	1,372,985	1,244,259	91 %
Depreciation	580,030	457,951	122,079	27 %
Research and other	343,267	330,666	12,601	4 %
Total research and development expenses	\$ 35,413,649	\$ 26,507,872	\$ 8,905,777	34 %

R&D expenses for the nine months ended September 30, 2024 increased by approximately \$8.9 million, or 34%, compared to the nine months ended September 30, 2023. The increase was primarily driven by the following:

- \$3.3 million increase in compensation and other personnel expenses primarily due to increases in headcount;
- \$2.3 million increase in DMD (deramiocele) program-related expenses primarily related to our HOPE-3 clinical trial, our HOPE-2 OLE clinical trial and expanded manufacturing production efforts for deramiocele in preparation for potential commercial launch;
- \$1.0 million increase in research expenses related to our exosomes platform primarily related to our collaboration with NIAID;
- \$0.9 million increase in facility expenses primarily related to expanded leased space; and
- \$1.2 million increase in stock-based compensation expense primarily due to increases in headcount.

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

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

	Three months ended September 30,		Change (\$)	Change (%)
	2024	2023		
Stock-based compensation	\$ 1,274,238	\$ 1,235,219	\$ 39,019	3 %
Compensation and other personnel expenses	1,049,146	845,332	203,814	24 %
Professional services	506,525	489,732	16,793	3 %
Facility expenses	79,978	67,076	12,902	19 %
Depreciation	160,440	113,677	46,763	41 %
Other corporate expenses	393,328	270,414	122,914	45 %
Total general and administrative expenses	\$ 3,463,655	\$ 3,021,450	\$ 442,205	15 %

G&A expenses for the three months ended September 30, 2024 increased by approximately \$0.4 million, or 15%, compared to the three months ended September 30, 2023. The increase was primarily driven by the following:

- \$0.2 million increase in compensation and other personnel expenses due to increases in headcount; and
- \$0.1 million increase in other corporate expenses.

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	Nine months ended September 30,		Change (\$)	Change (%)
	2024	2023		
Stock-based compensation	\$ 4,852,244	\$ 4,157,704	\$ 694,540	17 %
Compensation and other personnel expenses	2,664,553	2,579,847	84,706	3 %
Professional services	1,290,693	1,288,883	1,810	0 %
Facility expenses	231,111	195,233	35,878	18 %
Depreciation	469,479	303,324	166,155	55 %
Other corporate expenses	1,085,228	853,681	231,547	27 %
Total general and administrative expenses	<u>\$ 10,593,308</u>	<u>\$ 9,378,672</u>	<u>\$ 1,214,636</u>	<u>13 %</u>

G&A expenses for the nine months ended September 30, 2024 increased by approximately \$1.2 million, or 13%, compared to the nine months ended September 30, 2023. The increase was primarily driven by the following:

- \$0.7 million increase in stock-based compensation expense primarily due to increases in headcount;
- \$0.1 million increase in compensation and other personnel expenses related to increases in headcount;
- \$0.2 million increase in depreciation primarily related to leasehold improvements of our San Diego headquarters; and
- \$0.2 million increase in other corporate expenses.

Other Income

Investment Income. Investment income for both the three months ended September 30, 2024 and 2023 was approximately \$0.5 million. Investment income for the nine months ended September 30, 2024 and 2023 was approximately \$1.5 million and approximately \$1.3 million, respectively. The increase in investment income for the three and nine months ended September 30, 2024 as compared to the three and nine months ended September 30, 2023 is due to increased interest rates and the higher principal balance in our marketable securities, savings and money market fund accounts.

Products Under Active Development

Deramioceol for the treatment of DMD – We are currently conducting our HOPE-3, Phase 3 study for DMD and our ongoing OLE study of the HOPE-2 trial for which we expect to spend approximately \$30.0 million to \$35.0 million in 2024. The expenses for our DMD program will include costs for personnel, clinical, regulatory and manufacturing-related expenses, including expenses related to the scale-up for potential commercial scale manufacturing if our deramioceol product is approved.

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

Our expenditures on current and future clinical development programs, particularly our deramioceol and exosomes programs, cannot be predicted with any significant degree of certainty as they are dependent on the results of our current trials and our ability to secure additional funding and a strategic partner. Further, we cannot predict with any significant degree of certainty the amount of time which will be required to complete our clinical trials, the costs of completing research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during manufacturing and clinical development and as a result of a variety of other factors, including:

- the number of trials and studies in a clinical program;
- the number of patients who participate in the trials;
- the number of sites included in the trials;

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- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;
- the costs of manufacturing our product candidates;
- the availability of necessary materials required to make our product candidates;
- the costs, requirements and timing of, and the ability to secure, regulatory approvals; and
- the availability and cost of facilities needed to manufacture our products.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of September 30, 2024 and December 31, 2023 and our net increase (decrease) in cash and cash equivalents for the nine months ended September 30, 2024 and 2023 and is intended to supplement the more detailed discussion that follows. The amounts stated in the tables below are expressed in thousands.

Liquidity and capital resources	September 30, 2024	December 31, 2023
Cash and cash equivalents	\$ 68,377	\$ 14,695
Marketable securities	\$ 16,651	\$ 24,793
Working capital	\$ 65,348	\$ 19,586
Stockholders' equity	\$ 68,265	\$ 22,601

Cash flow data	Nine months ended September 30,	
	2024	2023
Cash provided by (used in):		
Operating activities	\$ (25,199)	\$ (14,003)
Investing activities	7,198	10,971
Financing activities	71,684	2,413
Net increase (decrease) in cash and cash equivalents	\$ 53,683	\$ (619)

Our total cash, cash equivalents and marketable securities as of September 30, 2024 were approximately \$85.0 million compared to approximately \$39.5 million as of December 31, 2023. The increase in cash, cash equivalents and marketable securities from December 31, 2023 to September 30, 2024 is primarily due to equity financings through our at-the-market offering and \$15.0 million private placement with Nippon Shinyaku. As of September 30, 2024, we had approximately \$24.7 million in total liabilities, of which approximately \$13.1 million relates to deferred revenue, and approximately \$65.3 million in net working capital.

Cash used in operating activities was approximately \$25.2 million and approximately \$14.0 million for the nine months ended September 30, 2024 and 2023, respectively. The increase of approximately \$11.2 million in cash used in operating activities is due to approximately \$11.8 million increase in net loss for the nine months ended September 30, 2024 as compared to the same period in 2023. Furthermore, there was an increase of approximately \$1.9 million in stock-based compensation and a decrease of approximately \$1.6 million in accounts payable and accrued expenses for the nine months ended September 30, 2024 as compared to the same period in 2023. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, including if we expand our platform technology portfolio, engage in further research and development activities, and, in particular, conduct preclinical studies and clinical trials, we expect to continue incurring substantial losses.

We had cash flow provided by investing activities of approximately \$7.2 million and approximately \$11.0 million for the nine months ended September 30, 2024, and 2023, respectively. The change in investing activities for the nine months ended September 30, 2024 as compared to the same period of 2023 is due to the net effect from purchases, sales and maturities of marketable securities and the decrease of approximately \$0.4 million in leasehold improvements.

We had cash flow provided by financing activities of approximately \$71.7 million and approximately \$2.4 million for the nine months ended September 30, 2024 and 2023, respectively. The increase in cash provided by financing activities for the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023 is due

to the net proceeds from the sale of common stock under our at-the-market program and Nippon Shinyaku private placement.

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

- the progress of our clinical and research activities;
- the number and scope of our clinical and research programs;
- the progress and success of our preclinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to successfully manufacture product for our clinical trials and potential commercial use;
- the availability of materials necessary to manufacture our product candidates;
- the costs of manufacturing our product candidates, and the progress of efforts with parties with whom we may enter into commercial manufacturing agreements, if necessary;
- our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;
- additional costs associated with maintaining licenses and insurance;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of obtaining marketing approval both in the United States and in countries outside of the United States.

Collaborations

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

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

Under the terms of the U.S. Distribution Agreement, Capricor will be responsible for the clinical development and manufacturing of deramiocel. Nippon Shinyaku and NS Pharma, Inc. (its wholly-owned U.S. subsidiary) will be responsible for the distribution of deramiocel in the United States. Pursuant to the U.S. Distribution Agreement, Capricor received an upfront payment of \$30.0 million in 2022. The first milestone payment of \$10.0 million was paid upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. Capricor received this milestone payment from Nippon Shinyaku in January 2024. Additionally, there are potential milestones totaling up to \$90.0 million leading up to and including the BLA approval. Further, there are various potential sales-based milestones, if commercialized, tied to the achievement of certain sales thresholds for annual net sales of deramiocel of up to \$605.0 million.

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

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

Under the terms of the Japan Distribution Agreement, Capricor received an upfront payment of \$12.0 million in the first quarter of 2023 and in addition, Capricor will potentially receive additional development and sales-based milestone payments of up to approximately \$89.0 million, subject to foreign currency exchange rates, and a meaningful double-digit share of product revenue. Nippon Shinyaku will be responsible for the distribution of deramiocel in Japan. Capricor will

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

Binding Term Sheet with Nippon Shinyaku (Territory: Europe)

On September 16, 2024, Capricor entered into a Binding Term Sheet (the “Term Sheet”) with Nippon Shinyaku for the commercialization and distribution of deramiocel for the treatment of DMD in the European region, as defined in the Term Sheet. Subject to finalization of a definitive agreement, under the terms of the Term Sheet, Capricor would be responsible for the development and manufacturing of deramiocel for potential approval in the European region. Nippon Shinyaku would be responsible for the sales and distribution of deramiocel in the European region. Subject to regulatory approval, Capricor would receive a double-digit share of product revenue and additional development and sales-based milestone payments. If the definitive agreement is entered into on the same economic terms as the term sheet, Capricor will receive an upfront payment of \$20.0 million upon execution of the definitive agreement, with potential additional development and sales-based milestone payments of up to \$715.0 million.

Financing Activities by the Company

September 2023 Financing

On September 29, 2023, the Company entered into Securities Purchase Agreements, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the “Registered Direct Offering”), an aggregate of 4,935,621 shares of its common stock, par value \$0.001 per share, at a price per share of \$4.66 for an aggregate purchase price of approximately \$23.0 million. Each share of common stock offered was sold with a warrant to purchase one share of common stock at an exercise price of \$5.70 per share. Each warrant became exercisable beginning six months after issuance and will expire seven years from the date of issuance.

ATM Program

On June 21, 2021, the Company initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to \$75.0 million (the “ATM Program”), with the common stock to be distributed at the market prices prevailing at the time of sale. The ATM Program was established under a Common Stock Sales Agreement (the “Sales Agreement,”), with H.C. Wainwright & Co. LLC (“Wainwright”), under which we may, from time to time, issue and sell shares of our common stock through Wainwright as sales agent. The Sales Agreement provides that Wainwright will be entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold. All shares issued pursuant to the ATM Program were issued pursuant to our shelf registration statement on Form S-3 (File No. 333-254363), which was initially filed with the Securities and Exchange Commission (the “SEC”), on March 16, 2021, amended on June 15, 2021 and declared effective by the SEC on June 16, 2021. From June 21, 2021 through October 1, 2024, the Company sold an aggregate of 9,228,383 shares of common stock under the ATM Program at an average price of approximately \$8.13 per share for gross proceeds of approximately \$75.0 million which represents all amounts that were available to be sold. Effective October 1, 2024, the ATM Program was closed and terminated. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to Wainwright, as well as legal and accounting fees, in the aggregate amount of approximately \$2.4 million.

September 2024 Private Placement

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

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

October 2024 Underwritten Public Offering

On October 16, 2024, the Company entered into an underwriting agreement (the “Underwriting Agreement”) with Piper Sandler and Oppenheimer as representatives of the underwriters (the “Underwriters”), pursuant to which the Company agreed to sell and issue, in a public offering an aggregate of 5,073,800 shares of common stock, including the exercise in full of the underwriters’ option to purchase additional shares to cover over allotments, at a public offering price of \$17.00 per share for total gross proceeds of approximately \$86.3 million, before deducting underwriting commissions and other offering expenses payable by Capricor. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to the Underwriters, as well as legal and accounting fees in the aggregate amount of approximately \$5.5 million.

CIRM Grant Award

On June 16, 2016, Capricor entered into an award (the “CIRM Award”) with the California Institute for Regenerative Medicine (“CIRM”) in the amount of approximately \$3.4 million to fund, in part, Capricor’s Phase I/II HOPE-Duchenne clinical trial investigating deramiocel for the treatment of Duchenne muscular dystrophy-associated cardiomyopathy. Pursuant to terms of the CIRM Award, the disbursements were tied to the achievement of specified operational milestones. In addition, the terms of the CIRM Award included a co-funding requirement pursuant to which Capricor was required to spend approximately \$2.3 million of its own capital to fund the CIRM funded research project. The CIRM Award is further subject to the conditions and requirements set forth in the CIRM Grants Administration Policy for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, California Code of Regulations (CCR) Sections 100600-100612, and the sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from the CIRM funded research as set forth in Title 17, CCR Section 100608. The maximum royalty on net commercial revenue that Capricor may be required to pay to CIRM is equal to nine times the total amount awarded and paid to Capricor.

After completing the CIRM funded research project and at any time after the award period end date (but no later than the ten-year anniversary of the date of the award), Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and development of the program at the time the election is made. On June 20, 2016, Capricor entered into a Loan Election Agreement with CIRM whereby, among other things, CIRM and Capricor agreed that if Capricor elects to convert the grant into a loan, the term of the loan could be up to five years from the date of execution of the applicable loan agreement; provided that the maturity date of the loan will not surpass the ten-year anniversary of the grant date of the CIRM Award. Beginning on the date of the loan, the loan shall bear interest on the unpaid principal balance, plus the interest that has accrued prior to the election point according to the terms set forth in the CIRM Loan Policy and CIRM Grants Administration Policy for Clinical Stage Projects (the “New Loan Balance”), at a per annum rate equal to the LIBOR rate for a three-month deposit in U.S. dollars, as published by the Wall Street Journal on the loan date, plus one percent. Interest shall be compounded annually on the outstanding New Loan Balance commencing with the loan date and the interest shall be payable, together with the New Loan Balance, upon the due date of the loan. Depending on the timing of our election, additional funds may be owed. If Capricor elects to convert the CIRM Award into a loan, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements. Capricor has not yet made its decision as to whether it will elect to convert the CIRM Award into a loan. If we elect to do so, Capricor would be required to repay the amounts awarded by CIRM, therefore the Company accounts for this award as a liability rather than income.

In 2019, Capricor completed all milestones and close-out activities associated with the CIRM Award and expended all funds received. As of September 30, 2024, Capricor’s liability balance for the CIRM Award was approximately \$3.4 million.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis, including research and development and clinical trial accruals, and stock-based compensation estimates. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Our actual results could differ from these estimates. We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our financial statements and accompanying notes.

Leases

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

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

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

The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

For real estate leases, the Company has elected the practical expedient under ASC 842 to account for the lease and non-lease components together for existing classes of underlying assets and allocates the contract consideration to the lease component only. This practical expedient is not elected for manufacturing facilities and equipment embedded in product supply arrangements.

Revenue Recognition

The Company applies ASU 606, *Revenue for Contracts from Customers*, which amended revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries. The Company has not yet achieved commercial sales of its drug candidates to date, however, the new standard is applicable to its distribution agreements.

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

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

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

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

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

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

Grant Income

The determination as to when income is earned is dependent on the language in each specific grant. Generally, we recognize grant income in the period in which the expense is incurred for those expenses that are deemed reimbursable

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

CIRM Grant Award

Capricor accounts for the disbursements under its CIRM Award as long-term liabilities. Capricor recognizes the CIRM grant disbursements as a liability as the principal is disbursed rather than recognizing the full amount of the grant award. After completing the CIRM funded research project and after the award period end date, Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and the stage of development at the time the election is made. In June 2016, Capricor entered into a Loan Election Agreement with CIRM whereby, among other things, CIRM and Capricor agreed that if Capricor elects to convert the grant into a loan, the term of the loan could be up to five years from the date of execution of the applicable loan agreement; provided that the maturity date of the loan will not surpass the ten-year anniversary of the grant date of the CIRM Award. Since Capricor may be required to repay some or all of the amounts awarded by CIRM, the Company accounts for this award as a liability rather than income.

Research and Development Expenses and Accruals

R&D expenses consist primarily of salaries and related personnel costs, supplies, clinical trial costs, patient treatment costs, rent for laboratories and manufacturing facilities, consulting fees, costs of personnel and supplies for manufacturing, costs of service providers for preclinical, clinical, 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 on-going development of our product candidates. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of the accrual policy is to match the recording of expenses in the financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials and other R&D activities are recognized based on our estimates of the degree of completion of the event or events specified in the applicable contract.

No adjustments for material changes in estimates have been recognized in any period presented.

Stock-Based Compensation

Our results include non-cash compensation expense as a result of the issuance of stock, stock options and warrants, as applicable. We have issued stock options to employees, directors and consultants under our five stock option plans: (i) the 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan (which superseded the 2006 Stock Option Plan), (the “2012 Plan”), (iii) the 2012 Non-Employee Director Stock Option Plan (the “2012 Non-Employee Director Plan”), (iv) the 2020 Equity Incentive Plan (the “2020 Plan”), and (v) the 2021 Equity Incentive Plan (the “2021 Plan”). At this time, the Company only issues options under the 2020 Plan and the 2021 Plan and no longer issues options under the 2006 Stock Option Plan, the 2012 Plan, or the 2012 Non-Employee Director Plan.

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

Stock options or other equity instruments to non-employees (including consultants) issued as consideration for goods or services received by us are accounted for based on the fair value of the equity instruments issued. The fair value of stock options is determined using the Black-Scholes option-pricing model. The Company calculates the fair value for non-qualified options as of the date of grant and expenses over the applicable vesting periods.

The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based conditions. Stock-based compensation expense is included in general and administrative expense or research and development expense, as applicable, in the Statements of Operations and Comprehensive Income (Loss). We expect to record additional non-cash compensation expense in the future, which may be significant.

Clinical Trial Expense

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

Recently Issued or Newly Adopted Accounting Pronouncements

In October 2023, the Financial Accounting Standards Board (“FASB”) issued ASU 2023-06, Disclosure Improvements: Codification Amendments in Response to the SEC’s Disclosure Update and Simplification Initiative. This standard was issued in response to the SEC’s disclosure update and simplification initiative, which affects a variety of topics within the Accounting Standards Codification. The amendments apply to all reporting entities within the scope of the affected topics unless otherwise indicated. The effective date for each amendment will be the date on which the SEC’s

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

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the SEC, did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statement presentation or disclosures.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Sensitivity

Our exposure to market risk for changes in interest rates relates primarily to our marketable securities and cash and cash equivalents. As of September 30, 2024, the fair value of our cash, cash equivalents and marketable securities was approximately \$85.0 million. Additionally, as of September 30, 2024, Capricor's investment portfolio was classified as cash, cash equivalents and marketable securities, which consisted primarily of money market funds which included short-term U.S. treasuries, bank savings and checking accounts.

The goal of our investment policy is to place our investments with highly rated credit issuers and limit the amount of credit exposure. We seek to improve the safety and likelihood of preservation of our invested funds by limiting default risk and market risk. Our investments may be exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments, if any. We will manage this exposure by performing ongoing evaluations of our investments. Due to the short-term maturities, if any, of our investments to date, their carrying value has always approximated their fair value. Our policy is to mitigate default risk by investing in high credit quality securities, and we currently do not hedge interest rate exposure. Due to our policy of making investments in U.S. treasury securities with primarily short-term maturities, we believe that the fair value of our investment portfolio would not be significantly impacted by a hypothetical 100 basis point increase or decrease in interest rates.

Item 4. Controls and Procedures.

We have adopted and maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that controls and procedures, no matter how well designed and operated, cannot provide absolute assurance of achieving the desired control objectives.

As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, we carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Controls over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings.

We are not involved in any material pending legal proceedings.

Item 1A. Risk Factors.

Part 1, Item 1A, “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on March 11, 2024, describes important risk factors that could cause our business, financial condition, results of operations and prospects to differ significantly from those suggested by forward-looking statements made in this Quarterly Report on Form 10-Q or otherwise presented by us from time to time. There have been no material changes in our risk factors from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on March 11, 2024.

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

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

- 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 [Term Sheet for Distribution of Deramiocel \(CAP-1002\) in Europe, by and between the Company and Nippon Shinyaku Co., Ltd.*+](#)

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10.2	Subscription Agreement, dated September 16, 2024, by and between the Company and Nippon Shinyaku Co., Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on September 17, 2024).
10.3	Registration Rights Agreement, dated September 16, 2024, by and between the Company and Nippon Shinyaku Co., Ltd. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on September 17, 2024).
10.4	Letter of Intent, dated September 16, 2024, by and between the Company and Nippon Shinyaku Co., Ltd. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on September 17, 2024).
10.5	Underwriting Agreement, dated October 16, 2024, by and among the Company, Piper Sandler & Co. and Oppenheimer & Co. Inc. (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, filed with the SEC on October 17, 2024).
10.6	Seventh Amendment to Facilities Lease, dated as of September 26, 2023, by and between Capricor, Inc. and Cedars-Sinai Medical Center.*
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, 2024 formatted in Inline eXtensible Business Reporting Language (iXBRL): (i) Condensed Consolidated Balance Sheets as of September 30, 2024 and December 31, 2023, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity (Deficit), (iv) Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

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

SIGNATURES

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

CAPRICOR THERAPEUTICS, INC.

Date: November 14, 2024

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

Date: November 14, 2024

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

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

TERM SHEET FOR DISTRIBUTION OF DERAMIOCEL (CAP-1002) IN EUROPE

August 27, 2024

Items	Contents
Party/Parties	Capricor Therapeutics, Inc. and Capricor, Inc. (hereinafter collectively “Capricor”) and Nippon Shinyaku Co., Ltd. (hereinafter “NS”)
Product	Cell therapy product using human allogeneic cardiosphere-derived cells, developed by Capricor and known as “deramiocel” (CAP-1002), used for the treatment of diseases and symptoms in humans for DMD.
Indication	Duchenne muscular dystrophy (DMD)
Territory	European Region European Region means [***].
Grant of Rights	<p>Capricor shall grant NS an exclusive right to market, promote, sell, commercialize, import and distribute the Products in the Territory including the right to appoint subdistributors with prior written notice to Capricor (with approval to be further outlined in the Definitive Agreement).</p> <p>If during the term of this Agreement, both Parties concur that any patent rights held by third parties would be infringed by the sale of Product in the Territory pursuant to this Agreement, Capricor shall use best efforts to acquire such rights at its sole responsibility and expense. Without any request from NS, Capricor agrees not to market, promote, sell, commercialize, import or distribute the Products in the Territory (including through an appointed distributor); provided Capricor shall have the right (directly and/or through its distributors) to promote, sell, commercialize, import and distribute the Products in the Territory: (a) if NS is unable to do so due to conditions to be set forth in the Agreement such as those conditions set forth in the U.S. agreement, and (b) for indications other than DMD.</p>
Agreement Term	<p>The Agreement shall commence on the date of the execution of the Agreement and, on a country-by-country basis in the Territory, continue in full force and effective until:</p> <ol style="list-style-type: none"> 1) The expiration date of the last to expire validated European patents that cover a deramiocel composition, manufacturing process, or DMD therapeutic use*; and 2) The expiration date of the regulatory exclusivity periods** for the Indication of the Product in each country of the Territory, <p>whichever comes later, unless earlier terminated pursuant to the terms of the Agreement.</p> <p>*The applicable patents and pending patent applications shall be listed on an exhibit to the Agreement.</p> <p>** Regulatory exclusivity periods mean period of the data protection and market exclusivity designated in the Article 14(11) of Regulation (EC) No 726/2004 or equivalent regulations.</p> <p>The terms for extension of the Agreement Term shall be discussed between the Parties in a negotiation of the Agreement.</p>
Clinical Study	After the execution of the Agreement, Capricor shall conduct all clinical studies of the Products for the Indication in the Territory if required by applicable regulatory authorities at its responsibility and expense.
Regulatory Approval	<p>In the Territory, Capricor shall be responsible for the development and the new drug application of the Products and shall make reasonably commercial efforts to obtain the regulatory approval of the Product as the marketing authorization holder. Also, Capricor shall be responsible for maintaining and controlling such regulatory approval.</p> <p>The timeline of the development and the new drug application of the Products in the Territory shall be agreed in the course of negotiations on the Agreement.</p>
Price Negotiation	<p>Capricor shall be responsible for applying for the pricing of the Product in the Territory through close consultation with NS. Capricor shall advise and shall keep NS informed on the status of the discussions with any governmental authorities on application for the list price and the reimbursement price for the Product in the Territory, including any material discussions with respect thereto and the price proposed by the authorities. The target price of the reimbursement price and the list price of the Product shall be agreed upon by the Parties on a country-by-country basis in the Territory prior to filing for the regulatory approval of the Product, prior to submission of the value dossier to the evaluation agency related to the drug price (including, but not limited to, Health Technology Assessment agencies) or the other timings as designated by NS. If the reimbursement price or the list price of the Product does not reach the respective target price agreed upon by the Parties, the Parties shall revise the terms and conditions of the Agreement in good faith to make performance of the Agreement commercially reasonable to the Parties.</p>

Pharmacovigilance	Capricor shall be responsible for any safety surveillance related to pharmacovigilance required for the Product in the Territory at its responsibility and expense. The details of the terms related hereto shall be set forth in the Pharmacovigilance Agreement. The global safety database of the Product shall be established at Capricor's responsibility and expense.
Supply of Commercial Products	Capricor shall manufacture and supply to NS quantities of commercial Products to satisfy NS's purchase requirements after packaging as the final product at the Transfer Price. Details regarding the supply of commercial Products shall be determined separately in a supply agreement and a quality agreement.
Initial Investment	NS shall make a payment to Capricor of 15 million U.S. dollars through a purchase of common shares of Capricor Therapeutics, Inc. pursuant to Article 2 of the Letter of Intent. The purchase price of the common shares shall be at a twenty percent (20%) premium over the sixty (60)-day VWAP preceding the execution date of the SPA.
Upfront Payment	NS shall make an upfront payment of 20 million U.S. dollars in cash upon the execution of the Agreement. Such payment shall be consideration for the costs and expenses incurred and to be incurred by Capricor in connection with any and all administrative, clinical, process development, CMC, regulatory and commercial development of the Product for the Territory. Timing of the payment of the 20 million U.S. dollars above shall be within 30 days from the date of the invoice to be issued by Capricor after the execution of the Agreement.
Development Milestones	NS shall pay to Capricor in U.S. dollars the following Development Milestones upon the first achievement of the following particular milestone events with respect to the Products: Timing of such payments shall be within 30 days from the date of the written notice of the respective event after the execution of the Agreement. [***]
Sales Milestones	Commencing in NS's fiscal year following achievement of marketing authorization, NS shall pay to Capricor the following Sales Milestones when the annual Net Sales of the commercial Products in the Territory (in total, not on a country by country basis) achieves the following amounts for the first time. The definition of the "Net Sales" shall be set forth in the Agreement. [***]
Minimum Sales Requirements	NS shall be required to sell a certain minimum number of Commercial Products in the Territory ("Minimum Sales Requirements") during each calendar year of the Agreement commencing with the year in which the Marketing Authorization is approved and ending upon the termination or expiration of the Agreement. The Minimum Sales Requirements shall be set forth in the Agreement.
Transfer Price of Commercial Products	During the Agreement Term, NS shall pay to Capricor the amount equivalent to CoG (Cost of Goods) plus a [***]% mark-up for the Products supplied to NS in the Territory as the Transfer Price.
Supply Price as Share of Revenues	On a country-by-country basis in the Territory, NS shall pay to Capricor on a quarterly basis the amount calculated by the following formula in the Territory during the Agreement Term as a share of revenues from sales of the Products. [***] If any biosimilar of the Product is launched in the Territory, the Parties shall consider reducing the Supply Price above to make performance of the Agreement commercially reasonable to the Parties.
Withholding Tax	NS shall deduct applicable withholding taxes, if any, from the amount paid to Capricor when NS pays the upfront payment, development milestone payments, sales milestone payments and revenue share, if required.
Representations and Warranties	Capricor represents and warrants that Capricor has the right to grant NS the rights specified in the "Grant of Rights" and "Trademark" above in the Territory. Capricor shall indemnify and hold NS and NS Indemnified Parties (to be defined in the Agreement) harmless from and against, and in respect of, any and all Third-Party Claims (to be defined in the Agreement) asserted against or incurred by, and any and all expenses payable by NS or any of NS Indemnified Parties that arises out of or relate to actual or alleged infringement of misappropriation alleged by third parties of patents, copyrights, trademarks, or other intellectual property rights by the using or selling of Product (except to the extent arising from NS's use or sale of the Product in a manner not approved by Capricor).
Trademarks	During the Agreement Term, the trademarks used for the Products ("Trademarks") shall be held by Capricor, and Capricor shall grant to NS the right to use such Trademarks in the Territory to the extent necessary to achieve the purposes of the Agreement without any charge to NS. In the Territory, Capricor shall file an application of, register, maintain and manage the Trademarks at Capricor's responsibility and expense.
Governing Law	The laws of the State of New York, USA.

Arbitration	New York, New York or Los Angeles, California Rules of Arbitration of the International Chamber of Commerce (“ICC Rules”) of ICC
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The other details shall be determined in a definitive agreement through mutual negotiation.

The definitive Agreement shall include, but not limited to, provisions for representation of warranty, indemnifications, reporting, forecasting, audit, product liability and confidentiality and also includes any ordinarily and customarily described provisions.

**SEVENTH
AMENDMENT TO
FACILITIES LEASE**

This Seventh Amendment to Facilities Lease (“**Seventh Amendment**”) is effective as of September 26, 2023 and is made by and between CEDARS-SINAI MEDICAL CENTER, a California nonprofit public benefit corporation (“**Landlord**”) and CAPRICOR, INC., a Delaware corporation (“**Tenant**”), with reference to the facts and circumstances set forth below.

A. Landlord and Tenant executed that certain Facilities Lease dated June 1, 2014 (the “**Lease**”), for the Premises described therein. Capitalized words and phrases contained in this Amendment shall have the same meanings ascribed to them in the Lease or in subsequent amendments, as noted.

B. Landlord and Tenant executed a First Amendment to the Lease dated August 1, 2017, a Second Amendment to the Lease dated September 7, 2018; a Third Amendment to the Lease dated March 1, 2019; a Fourth Amendment to the Lease dated August 18, 2020; a Fifth Amendment to the Lease dated September 22, 2021; and, a Sixth Amendment to the Lease dated July 31, 2022.

C. Pursuant to the Sixth Amendment to the Lease, Tenant was granted an option to extend the Term of the Lease until to and including July 31, 2024 for the Davis Building Premises (defined in that Fourth Amendment to the Lease). Tenant exercised this option to extend.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant agree to amend the Lease in the following manner:

1. TERM. Article III of the Lease is hereby modified to include the following:

(a) Tenant is hereby granted and shall have, if Tenant is not then in default under the Lease, an option to extend the Term of the Lease for the Davis Building Premises for an additional twenty-four (24) month period to and including July 31, 2026 on the same terms, covenants, and conditions contained in this Lease.

2. RENT.

In the event the option described in Section 1(a) is exercised by Tenant, the following shall apply for such extended Term:

(a) Article IV of the Lease will be modified to include the following:

“Commencing August 1, 2024 and continuing through the end of the Term of the Lease, the Tenant’s Total Monthly Payment shall be \$11,027.70”.

(b) Any and all references to Total Monthly Payment in the Lease shall be amended to refer to this amount of \$11,027.70 for the extended term.

3. REAFFIRMATION. As modified hereby, the Lease is reaffirmed and ratified by the parties in its entirety.

IN WITNESS WHEREOF, the parties have executed this Fourth Amendment as of the date set forth above.

Cedars-Sinai Medical Center
/s/ Nicole A. Leonard, JD, MBA

Name: Nicole A. Leonard, JD, MBA
Title: Vice President, Research

Capricor, Inc.
/s/ AJ Bergmann

Name: AJ Bergmann
Title: Chief Financial Officer

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 14, 2024

/s/ Linda Marbán, Ph.D.

Name: Linda Marbán, Ph.D.

Title: Chief Executive Officer and Principal Executive Officer

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 14, 2024

/s/ Anthony J. Bergmann

Name: Anthony J. Bergmann

Title: Chief Financial Officer, Principal Financial and Principal Accounting Officer

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, 2024 (the “**Report**”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: November 14, 2024

/s/ Linda Marbán, Ph.D.

Name: Linda Marbán, Ph.D.

Title: Chief Executive Officer and Principal Executive Officer

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, 2024 (the “**Report**”) fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: November 14, 2024

/s/ Anthony J. Bergmann

Name: Anthony J. Bergmann

Title: Chief Financial Officer, Principal Financial and Principal Accounting Officer
