**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, 2019**

**or**

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

**Commission File Number: 001-34058**

---

# CAPRICOR THERAPEUTICS, INC.

**(Exact Name Of Registrant As Specified In Its Charter)**

---

| **Delaware** | **88-0363465** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |

**8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211**
**(Address of principal executive offices including zip code)**

**(310) 358-3200**
**(Registrant's telephone number, including area code)**

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

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

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

| | |
|---|---|
| Large accelerated filer ☐ | Accelerated filer ☐ |
| Non-accelerated filer ☒ | Smaller reporting company ☒ |
| | Emerging growth company ☐ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

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

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

As of November 8, 2019, there were 4,246,225 shares of the registrant's common stock, par value $0.001 per share, issued and outstanding.

**INDEX TO QUARTERLY REPORT ON FORM 10-Q**

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- expectation of our dates for commencement of clinical trials, investigational new drug filings and similar plans or projections;
- regulatory developments involving products, including the ability to obtain regulatory approvals or otherwise bring products to market;
- the regulatory approval of our drug candidates, including our ability to obtain and maintain orphan drug, rare pediatric and RMAT designations for our lead product candidate CAP-1002;
- our use of clinical research centers, third party manufacturers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- our ability to manufacture products for clinical and commercial use;
- our ability to protect our patents and other intellectual property;
- our ability to market any of our products;
- our projected operating losses;
- 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 continue as a going concern;
- our ability to complete our clinical trials;
- our ability to raise additional financing;
- our ability to attract and retain key personnel; and
- the volatility of our stock price.

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

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

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

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

## PART I — FINANCIAL INFORMATION

**Item 1. Financial Statements.**

### CAPRICOR THERAPEUTICS, INC.
### CONDENSED CONSOLIDATED BALANCE SHEETS

| | September 30, 2019 (unaudited) | December 31, 2018 |
|---|---|---|
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | $ 6,827,570 | $ 4,259,266 |
| Marketable securities | - | 2,997,150 |
| Restricted cash | 232,803 | 285,831 |
| Grant receivable | 101,254 | 204,868 |
| Prepaid expenses and other current assets | 129,161 | 724,184 |
| TOTAL CURRENT ASSETS | 7,290,788 | 8,471,299 |
| PROPERTY AND EQUIPMENT, net | 474,699 | 574,206 |
| OTHER ASSETS | | |
| Intangible assets, net of accumulated amortization of $242,368 and $209,910, respectively | 17,314 | 49,772 |
| Other assets | 124,614 | 151,788 |
| TOTAL ASSETS | $ 7,907,415 | $ 9,247,065 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES | | |
| Accounts payable and accrued expenses | $ 947,608 | $ 1,148,853 |
| Accounts payable and accrued expenses, related party | 13,114 | 106,366 |
| TOTAL CURRENT LIABILITIES | 960,722 | 1,255,219 |
| LONG-TERM LIABILITIES | | |
| CIRM liability | 3,376,259 | 3,376,259 |
| TOTAL LONG-TERM LIABILITIES | 3,376,259 | 3,376,259 |
| TOTAL LIABILITIES | 4,336,981 | 4,631,478 |
| COMMITMENTS AND CONTINGENCIES (NOTE 6) | | |
| STOCKHOLDERS' EQUITY | | |
| Preferred stock, $0.001 par value, 5,000,000 shares authorized, none issued and outstanding | - | - |
| Common stock, $0.001 par value, 50,000,000 shares authorized, 4,174,856 and 3,138,748 shares issued and outstanding, respectively | 4,175 | 3,138 |
| Additional paid-in capital | 76,477,572 | 71,338,970 |
| Accumulated other comprehensive income | - | 12,393 |
| Accumulated deficit | (72,911,313) | (66,738,914) |
| TOTAL STOCKHOLDERS' EQUITY | 3,570,434 | 4,615,587 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | $ 7,907,415 | $ 9,247,065 |

See accompanying notes to the unaudited condensed consolidated financial statements.

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

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| REVENUE | | | | |
| Revenue | $ 142,071 | $ 219,249 | $ 782,928 | $ 1,023,274 |
| OPERATING EXPENSES | | | | |
| Research and development | 857,764 | 3,131,999 | 4,313,056 | 9,217,423 |
| General and administrative | 911,968 | 1,259,180 | 2,720,391 | 3,826,972 |
| TOTAL OPERATING EXPENSES | 1,769,732 | 4,391,179 | 7,033,447 | 13,044,395 |
| LOSS FROM OPERATIONS | (1,627,661) | (4,171,930) | (6,250,519) | (12,021,121) |
| OTHER INCOME (EXPENSE) | | | | |
| Investment income | 21,061 | 35,792 | 80,840 | 89,905 |
| Loss on disposal of fixed asset | - | - | (2,720) | - |
| NET LOSS | (1,606,600) | (4,136,138) | (6,172,399) | (11,931,216) |
| OTHER COMPREHENSIVE INCOME (LOSS) | | | | |
| Net unrealized gain (loss) on marketable securities | - | 1,922 | (12,393) | 8,587 |
| COMPREHENSIVE LOSS | $ (1,606,600) | $ (4,134,216) | $ (6,184,792) | $ (11,922,629) |
| Net loss per share, basic and diluted | $ (0.43) | $ (1.35) | $ (1.76) | $ (4.13) |
| Weighted average number of shares, basic and diluted | 3,746,801 | 3,060,988 | 3,500,002 | 2,886,255 |

See accompanying notes to the unaudited condensed consolidated financial statements.

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

| | COMMON STOCK | | | | | |
|---|---|---|---|---|---|---|
| | SHARES | AMOUNT | ADDITIONAL PAID-IN CAPITAL | OTHER COMPREHENSIVE INCOME (LOSS) | ACCUMULATED DEFICIT | TOTAL STOCKHOLDERS' EQUITY |
| **Balance at December 31, 2018** | 3,138,748 | $ 3,138 | $ 71,338,970 | $ 12,393 | $ (66,738,914) | $ 4,615,587 |
| Issuance of common stock, net of fees | 227,357 | 228 | 1,433,059 | - | - | 1,433,287 |
| Stock-based compensation | - | - | 223,166 | - | - | 223,166 |
| Unrealized loss on marketable securities | - | - | - | (12,393) | - | (12,393) |
| Net loss | - | - | - | - | (2,519,345) | (2,519,345) |
| **Balance at March 31, 2019** | 3,366,105 | 3,366 | 72,995,195 | - | (69,258,259) | 3,740,302 |
| Issuance of common stock, net of fees | 100,553 | 100 | 543,039 | - | - | 543,139 |
| Stock-based compensation | - | - | 124,217 | - | - | 124,217 |
| Fractional shares eliminated pursuant to reverse stock split | (27) | - | (193) | - | - | (193) |
| Stock options exercised | 828 | 1 | 2,771 | - | - | 2,772 |
| Net loss | - | - | - | - | (2,046,454) | (2,046,454) |
| **Balance at June 30, 2019** | 3,467,459 | 3,467 | 73,665,029 | - | (71,304,713) | 2,363,783 |
| Issuance of common stock, net of fees | 707,397 | 708 | 2,587,275 | - | - | 2,587,983 |
| Stock-based compensation | - | - | 225,268 | - | - | 225,268 |
| Net loss | - | - | - | - | (1,606,600) | (1,606,600) |
| **Balance at September 30, 2019** | 4,174,856 | $ 4,175 | $ 76,477,572 | $ - | $ (72,911,313) | $ 3,570,434 |

| | COMMON STOCK | | | | | |
|---|---|---|---|---|---|---|
| | SHARES | AMOUNT | ADDITIONAL PAID-IN CAPITAL | OTHER COMPREHENSIVE INCOME (LOSS) | ACCUMULATED DEFICIT | TOTAL STOCKHOLDERS' EQUITY |
| **Balance at December 31, 2017** | 2,627,049 | $ 2,626 | $ 62,760,428 | $ 11,620 | $ (51,547,819) | $ 11,226,855 |
| Issuance of common stock, net of fees | 131,178 | 131 | 2,373,347 | - | - | 2,373,478 |
| Stock-based compensation | 1,250 | 1 | 457,611 | - | - | 457,612 |
| Unrealized gain on marketable securities | - | - | - | 8,709 | - | 8,709 |
| Stock options exercised | 37,605 | 38 | 139,102 | - | - | 139,140 |
| Net loss | - | - | - | - | (3,671,530) | (3,671,530) |
| **Balance at March 31, 2018** | 2,797,082 | 2,796 | 65,730,488 | 20,329 | (55,219,349) | 10,534,264 |
| Issuance of common stock, net of fees | 200,666 | 201 | 2,775,198 | - | - | 2,775,399 |
| Stock-based compensation | 1,666 | 2 | 446,731 | - | - | 446,733 |
| Unrealized gain on marketable securities | - | - | - | (2,044) | - | (2,044) |
| Net loss | - | - | - | - | (4,123,548) | (4,123,548) |
| **Balance at June 30, 2018** | 2,999,414 | 2,999 | 68,952,417 | 18,285 | (59,342,897) | 9,630,804 |
| Issuance of common stock, net of fees | 75,454 | 75 | 1,053,326 | - | - | 1,053,401 |
| Stock-based compensation | - | - | 430,433 | - | - | 430,433 |
| Unrealized loss on marketable securities | - | - | - | 1,922 | - | 1,922 |
| Net loss | - | - | - | - | (4,136,138) | (4,136,138) |
| **Balance at September 30, 2018** | 3,074,868 | $ 3,074 | $ 70,436,176 | $ 20,207 | $ (63,479,035) | $ 6,980,422 |

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, | |
|---|---|---|
| | 2019 | 2018 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | $ (6,172,399) | $ (11,931,216) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Loss on disposal of fixed asset | 2,720 | - |
| Depreciation and amortization | 129,245 | 114,357 |
| Stock-based compensation | 572,651 | 1,334,778 |
| Change in assets - (increase) decrease: | | |
| Receivables | 103,614 | 171,986 |
| Prepaid expenses and other current assets | 595,023 | 74,742 |
| Other assets | 27,174 | (61,333) |
| Change in liabilities - increase (decrease): | | |
| Accounts payable and accrued expenses | (201,245) | 247,537 |
| Accounts payable and accrued expenses, related party | (93,252) | (42,077) |
| NET CASH USED IN OPERATING ACTIVITIES | (5,036,469) | (10,091,226) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchase of marketable securities | (15,243) | (15,000,733) |
| Proceeds from sales and maturities of marketable securities | 3,000,000 | 17,000,000 |
| Purchases of property and equipment | - | (332,081) |
| NET CASH PROVIDED BY INVESTING ACTIVITIES | 2,984,757 | 1,667,186 |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Net proceeds from sale of common stock | 4,564,409 | 6,202,278 |
| Repurchase of fractional shares pursuant to reverse stock split | (193) | - |
| Proceeds from stock options | 2,772 | 139,140 |
| NET CASH PROVIDED BY FINANCING ACTIVITIES | 4,566,988 | 6,341,418 |
| NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH | 2,515,276 | (2,082,622) |
| Cash, cash equivalents, and restricted cash balance at beginning of period | 4,545,097 | 6,882,137 |
| Cash, cash equivalents, and restricted cash balance at end of period | $ 7,060,373 | $ 4,799,515 |
| SUPPLEMENTAL DISCLOSURES: | | |
| Interest paid in cash | $ - | $ - |
| Income taxes paid in cash | $ - | $ - |

See accompanying notes to the unaudited condensed consolidated financial statements.

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

## 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Capricor Therapeutics, Inc., a Delaware corporation (referred to herein as "Capricor Therapeutics" or the "Company"), is a clinical-stage biotechnology company focused on the discovery, development and commercialization of innovative cell and exosome-based therapies for the treatment of diseases, with a focus on Duchenne muscular dystrophy ("DMD") and other rare disorders. Capricor, Inc. ("Capricor"), a wholly-owned subsidiary of Capricor Therapeutics, was founded in 2005 as a Delaware corporation based on the innovative work of its founder, Eduardo Marbán, M.D., Ph.D. After completion of a merger between Capricor and a subsidiary of Nile Therapeutics, Inc., a Delaware corporation ("Nile"), on November 20, 2013, Capricor became a wholly-owned subsidiary of Nile and Nile formally changed its name to Capricor Therapeutics, Inc. Capricor Therapeutics, together with its subsidiary, Capricor, have four drug candidates, two of which are in various stages of active 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 29, 2019, and as amended by the Company's Amendment No. 1 to Annual Report on Form 10-K/A filed with the SEC on April 1, 2019, from which the December 31, 2018 consolidated balance sheet has been derived. Interim results are not necessarily indicative of the results that may be expected for the year ending December 31, 2019.

Basis of Consolidation

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

Liquidity

The Company has historically financed its research and development activities as well as operational expenses from equity financings, government grants, a payment from Janssen Biotech, Inc. ("Janssen") pursuant to a Collaboration Agreement with Janssen and a loan award and a grant from the California Institute for Regenerative Medicine ("CIRM").

Cash, cash equivalents and marketable securities as of September 30, 2019 were approximately $6.8 million, compared to approximately $7.3 million as of December 31, 2018. The Company has entered into various Common Stock Sales Agreements with H.C. Wainwright & Co. LLC ("Wainwright") to create at-the-market equity programs under which the Company from time to time offered and sold shares of its common stock, par value $0.001 per share. From October 19, 2017 to September 30, 2019, through the use of these programs, the Company has raised gross proceeds of approximately $14.4 million (see Note 2 – "Stockholders' Equity").

Additionally, the Company has been awarded various grant and loan awards, which fund, in part, various pre-clinical and clinical activities (see Note 5 – "Government Grant Awards"). As of September 30, 2019, the Company has approximately $0.3 million remaining available under its grants and awards for disbursement, pursuant to the terms of the awards.

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

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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

- the timing and costs associated with its clinical trials and pre-clinical studies;
- the timing and costs associated with the manufacturing of its product candidates;
- the timing and costs associated with commercialization of its product candidates;
- the number and scope of its research programs; and
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights.

Based on the Company's current estimates and largely dependent on our decisions with respect to our DMD program, the Company believes it has sufficient cash to fund operations through at least the second quarter of 2020. In the first quarter of 2019, Capricor made certain operational adjustments to reduce expenses by slowing down certain R&D efforts, decreasing headcount, and implementing budget restrictions in order to preserve cash resources which allowed the Company to extend its available cash. Based on the Company's available cash resources, the Company does not have sufficient cash on hand to support current operations for at least the next twelve months from the date of filing this Report on Form 10-Q. Therefore, there is substantial doubt about the Company's ability to continue as a going concern.

The Company's options to address its financial position include potentially seeking additional financing primarily from, but not limited to, the sale and issuance of equity or debt securities, the licensing or sale of its technology and other assets, and from government grants. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

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

Reverse Stock Split

On June 4, 2019, the Company effected a reverse stock split of its outstanding shares of common stock at a ratio of one-for-ten pursuant to a Certificate of Amendment to the Company's Certificate of Incorporation filed with the Secretary of State of the State of Delaware. The reverse stock split was reflected on the Nasdaq Capital Market ("Nasdaq") beginning with the opening of trading on June 5, 2019. The primary purpose of the reverse stock split, which was approved by the Company's stockholders at the Company's Annual Stockholders Meeting on May 29, 2019, was to enable the Company to regain compliance with the $1.00 minimum bid price requirement for continued listing on Nasdaq. Pursuant to the reverse stock split, every ten shares of the Company's issued and outstanding shares of common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value per share of the common stock. Unless otherwise indicated, all share and per share amounts of the common stock included in the accompanying condensed consolidated financial statements have been retrospectively adjusted to give effect to the reverse stock split for all periods presented, including reclassifying an amount equal to the reduction in par value to additional paid-in capital. Amounts of common stock resulting from the reverse stock split were rounded down to the nearest whole share and any resulting fractional shares were cancelled for cash. The number of authorized shares of the Company's common stock remained unchanged. The reverse stock split affected all issued and outstanding shares of the Company's common stock, and the respective numbers of shares of common stock underlying outstanding stock options, outstanding warrants and the Company's equity incentive plans were proportionately adjusted.

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. The most sensitive estimates relate to the recoverability and fair value of intangible assets and the assumptions used to estimate stock-based compensation expense. Management uses its historical records and knowledge of its business in making these estimates. Accordingly, actual results may differ from these estimates.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets that total the same such amounts shown in the condensed consolidated statements of cash flows.

| | September 30, 2019 | September 30, 2018 |
|---|---|---|
| Cash and cash equivalents | $ 6,827,570 | $ 4,377,797 |
| Restricted cash | 232,803 | 421,718 |
| Total cash, cash equivalents, and restricted cash shown in the statements of cash flows | $ 7,060,373 | $ 4,799,515 |

For the nine months ended September 30, 2019, the Company had an outstanding letter of credit for $232,803 as a security deposit for its operating lease agreement for corporate office space (see Note 6 – “Commitments and Contingencies”). The Company is required to maintain this deposit for the duration of the lease agreement and this deposit represents the amount of the Company’s restricted cash for that period. In contrast, for the nine months ended September 30, 2018, restricted cash represents funds received under a CIRM award (the “CIRM Award”) (see Note 5 – “Government Grant Awards”). Restricted cash funds are to be allocated to the research costs as incurred. Generally, a reduction of restricted cash occurs when the Company deems certain costs are attributable to the respective award.

Marketable Securities

The Company determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company’s marketable securities are considered as available-for-sale and carried at estimated fair values. Realized gains and losses on the sale of debt and equity securities are determined using the specific identification method. Unrealized gains and losses on available-for-sale securities are excluded from net income (loss) and reported in accumulated other comprehensive income (loss) as a separate component of stockholders’ equity.

Property and Equipment

Property and equipment are stated at cost. Repairs and maintenance costs are expensed in the period incurred. Depreciation is computed using the straight-line method over the related estimated useful life of the asset, which such estimated useful lives range from five to seven years. Leasehold improvements are depreciated on a straight-line basis over the shorter of the useful life of the asset or the lease term. Depreciation was $96,787 and $81,900 for the nine months ended September 30, 2019 and 2018, respectively.

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

Property and equipment, net consisted of the following:

| | September 30, 2019 | December 31, 2018 |
|---|---|---|
| Furniture and fixtures | $ 46,709 | $ 46,709 |
| Laboratory equipment | 931,166 | 936,480 |
| Leasehold improvements | 47,043 | 47,043 |
| | 1,024,918 | 1,030,232 |
| Less accumulated depreciation | (550,219) | (456,026) |
| Property and equipment, net | $ 474,699 | $ 574,206 |

Intangible Assets

Amounts attributable to intellectual property consist primarily of the costs associated with the acquisition of certain technologies, patents, pending patents and related intangible assets with respect to research and development activities. Certain intellectual property assets are stated at cost and are amortized on a straight-line basis over the respective estimated useful lives of the assets ranging from five to fifteen years. Total amortization expense was $32,457 for both the nine months ended September 30, 2019 and 2018. A summary of future amortization expense as of September 30, 2019 is as follows:

| Years ended | Amortization Expense |
|---|---|
| 2019 (3 months) | 10,819 |
| 2020 | 4,330 |
| 2021 | 2,165 |

The Company reviews goodwill and intangible assets at least annually for possible impairment. Goodwill and intangible assets are reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying value. No impairment was recorded for the nine months ended September 30, 2019 and 2018.

Revenue Recognition

For contracts completed as of December 31, 2017, revenue was recognized in accordance with ASC 605 and other superseded standards. The company applied ASU 606 using the modified retrospective approach for all contracts in process as of January 1, 2018.

*Government Research Grants*

Generally, government research grants that provide funding for research and development activities are recognized as income when the related expenses are incurred, as applicable. Because the terms of the CIRM Award allow Capricor to elect to convert the grant into a loan after the end of the project period, the CIRM Award is being classified as a liability rather than income (see Note 5 - “Government Grant Awards”). Grant income is due upon submission of reimbursement request. The transaction price varies for grant income based on the expenses incurred under the awards.

*Miscellaneous Income*

Revenue is recognized in connection with the delivery of doses which were developed as part of our past R&D efforts. Income is recorded when the Company has satisfied the obligations as identified in the contracts with the customer (see Note 8 – “Related Party Transactions”). Miscellaneous income is due upon billing. Miscellaneous income is based on contracts with fixed transaction prices.

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

Rent

Rent expense for the Company's leases, which generally have escalating rental amounts over the term of the lease, is recorded on a straight-line basis over the lease term. The difference between the rent expense and rent paid has been recorded as deferred rent in the consolidated balance sheet under accounts payable and accrued expenses. Rent is amortized on a straight-line basis over the term of the applicable lease, without consideration of renewal options.

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 $0.9 million and $3.1 million for the three months ended September 30, 2019 and 2018, respectively, and approximately $4.3 million and $9.2 million for the nine months ended September 30, 2019 and 2018, 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 $1.6 million and $4.1 million for the three months ended September 30, 2019 and 2018, respectively, and approximately $6.2 million and $11.9 million for the nine months ended September 30, 2019 and 2018, respectively. The Company's other comprehensive income (loss) is related to a net unrealized gain (loss) on marketable securities. For the three months ended September 30, 2019 and 2018, the Company's other comprehensive gain (loss) was zero and $1,922, respectively. For the nine months ended September 30, 2019 and 2018, the Company's other comprehensive income (loss) was $(12,393) and $8,587, respectively.

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. 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.

Loss per Share

The Company reports earnings per share in accordance with FSAB ASC 260-10,*Earnings per Share.* Basic earnings (loss) per share is computed by dividing income (loss) available to common shareholders by the weighted-average number of common shares 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 common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive.

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

For the three and nine months ended September 30, 2019 and 2018, warrants and options to purchase were 775,225 and 836,844 shares of common stock, respectively, which have been excluded from the computation of potentially dilutive securities. Potentially dilutive common shares, which primarily consist of stock options issued to employees, consultants, and directors as well as warrants issued, have been excluded from the diluted loss per share calculation because their effect is anti-dilutive.

Fair Value Measurements

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

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

The following tables summarize the fair value measurements by level for assets and liabilities measured at fair value on a recurring basis:

| | December 31, 2018 | | | |
|---|---|---|---|---|
| | Level I | Level II | Level III | Total |
| Marketable Securities | $ 2,997,150 | $ - | $ - | $ 2,997,150 |

Carrying amounts reported in the balance sheet of cash and cash equivalents, grants receivable, 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 February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which supersedes existing guidance on accounting for leases in *Leases (Topic 840)* and issued additional clarification throughout 2018. Under the new guidance, a lessee should recognize assets and liabilities that arise from its leases and disclose qualitative and quantitative information about its leasing arrangements. The Company elected the optional transition method to apply the standard as of January 1, 2019 as the effective date and therefore, did not apply the standard to comparative periods. The Company did not apply the recognition requirements to short-term leases and recognized those lease payments in the Consolidated Statements of Operations and Comprehensive Loss on a straight-line basis over the lease term. The Company also elected the available package of practical expedients in transition which allowed us to not re-assess whether existing or expired arrangements contain a lease, the lease classification of existing or expired leases, or whether previous initial direct costs would qualify for capitalization under the new lease standard. The adoption of this update did not have a material impact on the Company's financial statements.

## 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The Company early adopted ASU 2018-07 and all subsequent updates related to this topic on a prospective basis effective July 1, 2018. The adoption of this update did not have a material impact on the Company's financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808):* clarifying the interaction between Topic 808 and Topic 606. The amendments in the update clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account; adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 when an entity is assessing whether the collaborative arrangement or a party of the arrangement is within the scope of Topic 606; requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The amendments for this update are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of the new guidance on our consolidated financial statements.

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

Common Stock Sales Agreements

Since October 2017, the Company has entered into multiple Common Stock Sales Agreements with Wainwright establishing ATM programs by which Wainwright sold and may continue to sell common stock at the market prices prevailing at the time of sale. Wainwright is entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold plus reimbursement of certain expenses. These programs are referred to below as the "October 2017 ATM Program," the "July 2019 ATM Program," and the "August 2019 ATM Program" based on when each program was initiated.

*October 2017 ATM Program*

From October 19, 2017 through expiration of the October 2017 ATM Program on April 23, 2019, the Company sold an aggregate of 899,233 shares at an average price of approximately $13.04 per common share for gross proceeds of approximately $11.7 million. The Company paid 3.0% cash commission on the gross proceeds, plus reimbursement of expenses of Wainwright and legal fees in the aggregate amount of approximately $0.4 million.

*July 2019 ATM Program*

From July 22, 2019 through expiration of the July 2019 ATM Program on August 23, 2019, the Company sold an aggregate of 418,450 common shares under the July 2019 ATM Program at an average price of approximately $4.30 per common share for gross proceeds of approximately $1.8 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of Wainwright and legal fees in the aggregate amount of approximately $0.1 million.

*August 2019 ATM Program*

On August 29, 2019, the Company initiated the August 2019 ATM Program. Since August 29, 2019 and through November 8, 2019, the Company has sold an aggregate of 360,316 common shares under the August 2019 ATM Program at an average price of approximately $3.07 per common share for gross proceeds of approximately $1.1 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of Wainwright and legal fees in the aggregate amount of approximately $0.1 million.

## 2. STOCKHOLDER'S EQUITY (Continued)

Outstanding Shares

At September 30, 2019, the Company had 4,174,856 shares of common stock issued and outstanding.

## 3. STOCK AWARDS, WARRANTS AND OPTIONS

Warrants

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

| | Warrants Outstanding | | | |
|---|---|---|---|---|
| Grant Date | September 30, 2019 | December 31, 2018 | Exercise Price per Share | Expiration Date |
| 3/16/2016 | - | 84,607 | $ 45.00 | 3/16/2019 |
| | **-** | **84,607** | | |

Stock Options

The Company's Board of Directors (the "Board") has approved three 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"), and (iii) the 2012 Non-Employee Director Stock Option Plan (the "2012 Non-Employee Director Plan").

At the time the merger between Capricor and Nile became effective, 414,971 shares of common stock were reserved under the 2012 Plan for the issuance of stock options, stock appreciation rights, restricted stock awards and performance unit/share awards to employees, consultants and other service providers. Included in the 2012 Plan are the shares of common stock that were originally reserved under the 2006 Stock Option Plan. Under the 2012 Plan, each stock option granted will be designated in the award agreement as either an incentive stock option or a nonstatutory stock option. Notwithstanding such designation, however, to the extent that the aggregate fair market value of the shares with respect to which incentive stock options are exercisable for the first time by the participant during any calendar year (under all plans of the Company and any parent or subsidiary) exceeds $100,000, such options will be treated as nonstatutory stock options.

On June 2, 2016, at the Company's annual stockholder meeting, the stockholders approved a proposal to amend the 2012 Plan, to, among other things, increase the number of shares of common stock of the Company that may be issued under the 2012 Plan to equal the sum of 414,971 plus 2% of the outstanding shares of common stock as of December 31, 2015, with the number of shares that may be issued under the 2012 Plan automatically increasing thereafter on January 1 of each year, commencing with January 1, 2017, by 2% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year (rounded down to the nearest whole share). As of January 1, 2019, the maximum number of shares that may be issued under the 2012 Plan was 605,595 shares.

At the time the merger between Capricor and Nile became effective, 269,731 shares of common stock were reserved under the 2012 Non-Employee Director Plan for the issuance of stock options to members of the Board who are not employees of the Company.

Each of the Company's stock option plans are administered by the Board, or a committee appointed by 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. Currently, stock options are granted with an exercise price equal to the closing price of the Company's common stock on the date of grant, and generally vest over a period of one to four years. The term of stock options granted under each of the plans cannot exceed ten years.

The estimated weighted average fair value of the options granted during the three months ended September 30, 2019 and 2018 were approximately $2.73 and $10.53 per share, respectively. The estimated weighted average fair value of the options granted during the nine months ended September 30, 2019 and 2018 were approximately $2.73 and $13.09 per share, respectively.

**3. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)**

The Company estimates the fair value of each option award using the Black-Scholes option-pricing model. The Company used the following assumptions to estimate the fair value of stock options issued in the nine months ended September 30, 2019 and 2018:

| | September 30, 2019 | September 30, 2018 |
|---|---|---|
| Expected volatility | 106% - 128% | 137% - 145% |
| Expected term | 5 - 6 years | 5 - 6 years |
| Dividend yield | 0% | 0% |
| Risk-free interest rates | 1.4 – 1.6% | 2.3 – 3.0% |

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

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| General and administrative | $ 170,428 | $ 283,282 | $ 423,318 | $ 878,598 |
| Research and development | 54,840 | 147,151 | 149,333 | 409,932 |
| Total | $ 225,268 | $ 430,433 | $ 572,651 | $ 1,288,530 |

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. Historically, the Company periodically re-measured the fair value for non-qualified option grants recording an expense over the applicable vesting periods. However, in the third quarter of 2018, the Company early adopted ASU 2018-07. 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 estimated forfeitures at the date of grant.

The following is a schedule summarizing employee and non-employee stock option activity for the nine months ended September 30, 2019:

| | Number of Options | Weighted Average Exercise Price | Aggregate Intrinsic Value |
|---|---|---|---|
| Outstanding at January 1, 2019 | 701,287 | $ 16.18 | |
| Granted | 130,000 | 3.20 | |
| Exercised | (828) | 3.35 | |
| Expired/Cancelled | (75,234) | 29.50 | |
| Outstanding at September 30, 2019 | 755,225 | $ 12.63 | $ 113,682 |
| Exercisable at September 30, 2019 | 616,462 | $ 13.55 | $ 67,670 |

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.

The aggregate intrinsic value of options exercised was approximately $1,987 and $521,678 for the nine months ended September 30, 2019 and 2018, respectively.

## 4. CONCENTRATIONS

Cash Concentration

The Company has historically maintained checking accounts at two financial institutions. These accounts are each insured by the Federal Deposit Insurance Corporation for up to $250,000. Historically, the Company has not experienced any significant losses in such accounts and believes it is not exposed to any significant credit risk on cash, cash equivalents and marketable securities. As of September 30, 2019, the Company maintained approximately $6.6 million of uninsured deposits.

## 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 CAP-1002 for the treatment of Duchenne muscular dystrophy-associated cardiomyopathy. Pursuant to terms of the CIRM Award, the disbursements were tied to the achievement of specified operational milestones. If CIRM determines, in its sole discretion, that Capricor has not complied with the terms and conditions of the CIRM Award, CIRM may suspend or permanently cease disbursements or pursue other remedies as allowed by law. In addition, the terms of the CIRM Award include a co-funding requirement pursuant to which Capricor is required to spend approximately $2.3 million of its own capital to fund the CIRM funded research project. If Capricor fails to satisfy its co-funding requirement, the amount of the CIRM Award may be proportionately reduced. The CIRM Award is further subject to the conditions and requirements set forth in the CIRM Grants Administration Policy for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, California Code of Regulations (CCR) Sections 100600-100612, and the sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from the CIRM funded research as set forth in Title 17, CCR Section 100608. The maximum royalty on net commercial revenue that Capricor may be required to pay to CIRM is equal to nine times the total amount awarded and paid to Capricor.

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

On August 8, 2017, Capricor entered into an Amendment to the CIRM Notice of Award pursuant to which CIRM approved Capricor's request to use the remaining estimated project funds of the CIRM Award for technology transfer activities in support of the manufacture of CAP-1002 to a designated contract manufacturing organization ("CMO") to help enable Capricor to offer access to CAP-1002 to patients from the control arm of the HOPE-Duchenne trial via an open-label extension protocol. On September 7, 2018, Capricor entered into an Amendment to the CIRM Notice of Award pursuant to which CIRM added an additional operational milestone which would be satisfied by completion of certain activities related to technology transfer. On January 23, 2019, Capricor entered into an Amendment to the CIRM Notice of Award pursuant to which CIRM added an additional operational milestone which would be satisfied by completion of certain activities related to the HOPE-OLE clinical trial.

**5. GOVERNMENT GRANT AWARDS (Continued)**

In 2016, Capricor received $3.1 million under the terms of the CIRM Award. In September 2017, Capricor completed the second operational milestone tied to the last patient completing one year of follow-up, for which approximately $0.3 million was received by Capricor in November 2017. As of September 30, 2019, Capricor's liability balance for the CIRM Award was $3.4 million. In June 2019, Capricor completed all milestones associated with the CIRM Award and expended all funds received. In the third quarter of 2019, Capricor completed all final close-out documentation associated with this award.

NIH Grant Award (HLHS)

In September 2016, Capricor was approved for a grant from the National Institutes of Health ("NIH") to study CAP-2003 (cardiosphere-derived cell exosomes) for hypoplastic left heart syndrome (HLHS). Under the terms of the NIH grant, Capricor is eligible to receive disbursements in an amount up to approximately $4.2 million, subject to annual and quarterly reporting requirements as well as completion of the study objectives. As of June 30, 2019, approximately $0.7 million had been incurred under the terms of the NIH grant award. In the second quarter of 2019, the award was closed, and all filings completed with no additional expenses expected to be incurred.

U.S. Department of Defense Grant Award

In September 2016, Capricor was approved for a grant award from the Department of Defense in the amount of approximately $2.4 million to be used toward developing a scalable, commercially-ready process to manufacture CAP-2003. Under the terms of the award, disbursements will be made to Capricor over a period of approximately three years, subject to annual and quarterly reporting requirements. The Company was granted a no-cost extension until September 29, 2020 to be able to continue to utilize these funds. As of September 30, 2019, approximately $2.1 million has been incurred under the terms of the award.

**6. COMMITMENTS AND CONTINGENCIES**

Leases

Capricor leases space for its corporate offices from The Bubble Real Estate Company, LLC pursuant to a lease that was originally effective for a two-year period beginning July 1, 2013 with an option to extend the lease for an additional twelve months. Capricor subsequently entered into several amendments extending the term of the lease and modifying its terms. On January 11, 2019, Capricor entered into a Fourth Amendment to Lease (the "Fourth Lease Amendment") with The Bubble Real Estate Company, LLC. Under the terms of the Fourth Lease Amendment, the lease term extension commenced on January 1, 2019 and will end on December 31, 2019 with a base rent of $25,867 per month. The Company delivered to the landlord an unconditional, irrevocable, transferrable letter of credit effective April 1, 2019 in the amount of $232,803 to cover payments of rent for the remainder of the lease term. We are considering various options with respect to our office lease, which may include, extending our lease period, extending on a month-to-month basis, if possible, or finding a short-term lease in a different location.

Capricor leases facilities from Cedars-Sinai Medical Center ("CSMC") pursuant to a lease (the "Facilities Lease") that was originally effective for a three-year period beginning June 1, 2014. Capricor has subsequently entered into several amendments extending the term of the lease and modifying its terms. From August 1, 2017 through March 1, 2019, total monthly rent was $19,756. Effective March 1, 2019, the square footage of the leased premises was reduced, resulting in a rent reduction of approximately $4,000 per month. In July 2019, Capricor exercised an option to extend the term of the Facilities Lease for an additional 12-month period through July 31, 2020 with a monthly lease payment of $15,805. The Company has a further option to extend the Facilities Lease through July 31, 2021.

In addition, Capricor entered into a month-to-month lease agreement with University Center Lane Tenant, LLC, pursuant to which Capricor leased office space located in San Diego, California. The lease commenced March 1, 2018 and the rental payment was $4,190 per month. The Company terminated the lease effective February 28, 2019.

**6. COMMITMENTS AND CONTINGENCIES (Continued)**

Included within the table below, future minimum rental payments to related parties totaled $158,050. A summary of future minimum rental payments required under operating leases as of September 30, 2019 is as follows:

| Years ended | | Operating Leases |
|---|---|---|
| 2019 (3 months) | $ | 125,016 |
| 2020 | $ | 110,632 |

Expenses incurred under operating leases to unrelated parties for the three months ended September 30, 2019 and 2018 were $77,601 and $83,785, respectively, and $239,803 and $244,835 for the nine months ended September 30, 2019 and 2018, respectively. Expenses incurred under operating leases to related parties for each of the three months ended September 30, 2019 and 2018 were $47,415 and $59,268, respectively, and $150,147 and $177,804 for the nine months ended September 30, 2019 and 2018, respectively.

Legal Contingencies

The Company is not a party to any material legal proceedings at this time. From time to time, the Company may become involved in various legal proceedings that arise in the ordinary course of its business or otherwise.

Accounts Payable

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

Employee Severances

In the first quarter of 2019, the Board of Directors approved severance packages for all current full-time employees based on length of service and position ranging up to six months of their base salaries subject to certain conditions. No liability has been recorded as of September 30, 2019.

**7. LICENSE AGREEMENTS**

Capricor's Technology - CAP-1002, CAP-1001, CSps 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"), The Johns Hopkins University ("JHU") and 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. Capricor has a right of first negotiation, for a certain period of time, to obtain a license to any new and separate patent applications owned by the University of Rome utilizing cardiac stem cells in cardiac care.

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

**7. LICENSE AGREEMENTS (Continued)**

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 Agreement*

Capricor and JHU entered into an Exclusive License Agreement, effective June 22, 2006 (the "JHU License Agreement"), which provides for the grant of an exclusive, world-wide, royalty-bearing license by JHU to Capricor (with the right to sublicense) to develop and commercialize licensed products and licensed services under the licensed patent rights in all fields and a nonexclusive right to the know-how. In May 2009, the JHU License Agreement was amended to add additional patent rights to the JHU License Agreement in consideration of a payment to JHU and reimbursement of patent costs. Capricor and JHU executed a Second Amendment to the JHU License Agreement, effective as of December 20, 2013, pursuant to which, among other things, certain definitions were added or amended, the timing of certain obligations was revised and other obligations of the parties were clarified. Under the JHU License Agreement, Capricor is required to exercise commercially reasonable and diligent efforts to develop and commercialize licensed products covered by the licenses from JHU.

Pursuant to the JHU License Agreement, JHU was paid an initial license fee and, thereafter, Capricor is required to pay minimum annual royalties on the anniversary dates of the JHU License Agreement. The minimum annual royalties range from $5,000 on the first and second anniversary dates to $20,000 on the tenth anniversary date and thereafter. The minimum annual royalties are creditable against a low single-digit running royalty on net sales of products and net service revenues, which Capricor is also required to pay under the JHU License Agreement, which running royalty may be subject to further reduction in the event that Capricor is required to pay royalties on any patent rights to third parties in order to make or sell a licensed product. In addition, Capricor is required to pay a low double-digit percentage of the consideration received by it from sublicenses granted, and is required to pay JHU certain defined development milestone payments upon the successful completion of certain phases of its clinical studies and upon receiving approval from the U.S. Food and Drug Administration (the "FDA"). The development milestones range from $100,000 upon successful completion of a full Phase I clinical study to $1,000,000 upon full FDA market approval and are fully creditable against payments owed by Capricor to JHU on account of sublicense consideration attributable to milestone payments received from a sublicensee. The maximum aggregate amount of milestone payments payable under the JHU License Agreement, as amended, is $1,850,000. In May 2015, Capricor paid the development milestone related to Phase I that was owed to JHU pursuant to the terms of the JHU License Agreement.

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

*Cedars-Sinai Medical Center License Agreements*

*License Agreement for CDCs*

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

**7. LICENSE AGREEMENTS (Continued)**

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. The annual spending requirements ranged from $350,000 to $800,000 each year between 2010 and 2017 (with the exception of 2014, for which there was no annual spending requirement).

Pursuant to the Amended CSMC License Agreement, Capricor remains obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a low double-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third party for patent rights in connection with the royalty-bearing product. In 2010, Capricor discontinued its research under some of the patents.

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

On March 20, 2015, Capricor and CSMC entered into a First Amendment to the Amended CSMC License Agreement, pursuant to which the parties agreed to delete certain patent applications from the list of scheduled patents which Capricor determined not to be material to the portfolio.

On August 5, 2016, Capricor and CSMC entered into a Second Amendment to the Amended CSMC License Agreement (the "Second License Amendment"), pursuant to which the parties agreed to add certain patent applications to the schedule of patent rights set forth in the agreement. Under the Second License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes six additional patent applications; (ii) Capricor paid an upfront fee of $2,500; and (iii) Capricor reimbursed CSMC approximately $10,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent applications.

On December 26, 2017, Capricor entered into a Third Amendment to the Amended CSMC License Agreement thereby amending the CDCs License (the "Third License Amendment"). Under the Third License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes seven additional patent applications; and (ii) Capricor is required to reimburse CSMC approximately $50,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent rights.

On June 20, 2018, Capricor and CSMC entered into a Fourth Amendment to the Amended CSMC License Agreement (the "Fourth License Amendment"). Under the Fourth License Amendment, the description of scheduled patent rights has been replaced by a revised schedule that includes two additional patent applications.

**7. LICENSE AGREEMENTS (Continued)**

*License Agreement for Exosomes*

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

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

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

On February 27, 2015, Capricor and CSMC entered into a First Amendment to Exosomes License Agreement (the "First Exosomes License Amendment"). Under the First Exosomes License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes four additional patent applications; (ii) Capricor was required to pay CSMC an upfront fee of $20,000; (iii) Capricor was required to reimburse CSMC approximately $34,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent rights; and (iv) Capricor is required to pay CSMC certain defined product development milestone payments upon reaching certain phases of its clinical studies and upon receiving approval for a product from the FDA. The product development milestones range from $15,000 upon the dosing of the first patient in a Phase I clinical trial of a product to $75,000 upon receipt of FDA approval for a product. The maximum aggregate amount of milestone payments payable under the Exosomes License Agreement, as amended, is $190,000.

On June 10, 2015, Capricor and CSMC entered into a Second Amendment to Exosomes License Agreement, thereby amending the Exosomes License Agreement further to add an additional patent application to the Schedule of Patent Rights.

On August 5, 2016, Capricor and CSMC entered into a Third Amendment to the Exosomes License Agreement (the "Third Exosomes License Amendment"), pursuant to which the parties agreed to add certain patent applications to the schedule of patent rights under the agreement. Under the Third Exosomes License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes three additional patent applications; (ii) Capricor paid CSMC an upfront fee of $2,500; and (iii) Capricor reimbursed CSMC approximately $16,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent applications.

**7. LICENSE AGREEMENTS (Continued)**

On December 26, 2017, Capricor and CSMC entered into a Fourth Amendment to Exosomes License Agreement, thereby amending the Exosomes License (the "Fourth Exosomes License Amendment"). Under the Fourth Exosomes License Amendment, (i) the description of scheduled patent rights was replaced by a revised schedule that includes seven additional patent applications; (ii) Capricor is required to reimburse CSMC approximately $50,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent rights; and (iii) a schedule to the Exosomes License was modified to extend the milestone deadline for filing an IND for at least one product to December 31, 2018.

On June 20, 2018, Capricor and CSMC entered into a Fifth Amendment to the Exosomes License Agreement (the "Fifth License Amendment"). Under the Fifth License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes four additional patent applications; and (ii) Capricor is required to reimburse CSMC approximately $27,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent rights.

On September 25, 2018, Capricor and CSMC entered into a Sixth Amendment to the Exosomes License Agreement (the "Sixth License Amendment"). Under the Sixth License Amendment, the milestone deadline for filing an IND for at least one product has been extended to December 31, 2019. If the Company does not file an IND by December 31, 2019, or negotiate an additional extension of the milestone deadline, CSMC would have the option to convert the exclusive license to a non-exclusive license or to a co-exclusive license or terminate the license under Title 35, Section 203 of the United States Code. Prior to exercising such option, Capricor has the opportunity to cure the failure to file an IND for a period of 90 days after its receipt of written notice from CSMC of its intent to exercise its option.

**8. RELATED PARTY TRANSACTIONS**

Lease and Sub-Lease Agreement

As noted above, Capricor is a party to lease agreements with CSMC, which holds more than 5% of the outstanding capital stock of Capricor Therapeutics (see Note 6 – "Commitments and Contingencies"), and CSMC has served as an investigative site in Capricor's clinical trials. Additionally, Dr. Eduardo Marbán, who holds more than 5% of the outstanding capital stock of Capricor Therapeutics and participates as an observer at the Company's meetings of the Board of Directors, is the Director of the Cedars-Sinai Smidt Heart Institute, a co-founder of Capricor and the Chairman of the Company's Scientific Advisory Board.

On April 1, 2013, Capricor entered into a sublease with Reprise Technologies, LLC, a limited liability company which is wholly owned by Dr. Frank Litvack, the Company's Executive Chairman and member of its Board of Directors, for $2,500 per month. The sublease is on a month-to-month basis. For each of the three months periods ended September 30, 2019 and 2018, Capricor recognized $7,500 in sublease income from the related party. For each of the nine month periods ended September 30, 2019 and 2018, Capricor recognized $22,500 in sublease income from the related party. Sublease income is recorded as a reduction to general and administrative expenses.

Consulting Agreements

In 2013, Capricor entered into a Consulting Agreement with Dr. Frank Litvack, the Company's Executive Chairman and a member of its Board of Directors, whereby Capricor agreed to pay Dr. Litvack $10,000 per month for consulting services. The agreement is terminable upon 30 days' notice.

Payables to Related Party

At September 30, 2019 and December 31, 2018, the Company had accounts payable and accrued expenses to related parties totaling $13,114 and $106,366, respectively. CSMC accounts for $13,114 and $100,191 of the total accounts payable and accrued expenses to related parties as of September 30, 2019 and December 31, 2018, respectively. CSMC expenses relate to research and development costs. During the nine months ended September 30, 2019 and 2018, the Company paid CSMC approximately $288,000 and $570,000, respectively, for such costs.

**8. RELATED PARTY TRANSACTIONS (Continued)**

Related Party Clinical Trials

Capricor has agreed to provide cells for investigational purposes in two clinical trials sponsored by CSMC. These cells were developed as part of the Company's past research and development efforts. The first trial is known as "Regression of Fibrosis and Reversal of Diastolic Dysfunction in HFpEF Patients Treated with Allogeneic CDCs." Dr. Eduardo Marbán is the named principal investigator under the study. The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells." In both studies, Capricor will provide the necessary number of doses of cells and will receive a negotiated amount of monetary compensation which is estimated to be approximately $2.1 million over several years. For the three months ended September 30, 2019 and 2018, the Company recognized approximately $41,000 and $47,000, respectively, as revenue. For the nine months ended September 30, 2019 and 2018, the Company recognized approximately $324,000 and $257,000, respectively, as revenue. As of September 30, 2019, and December 31, 2018, approximately $8,000 and $269,000, respectively, is outstanding and recorded in prepaid expenses and other current assets.

Related Party Agreement

On May 10, 2018, Capricor and TrialTech Medical, Inc., a corporation in which Dr. Frank Litvack, our Executive Chairman and a director, is a co-founder, shareholder and chairman, entered into an agreement whereby TrialTech Medical, Inc. would provide clinical trial services to Capricor for its HOPE-2 clinical trial. In December 2018, Capricor ceased the use of those services. Total costs incurred under the agreement were approximately $42,600.

**9. SUBSEQUENT EVENTS**

Additional Sales Under August 2019 ATM Program

Subsequent to September 30, 2019 and through November 8, 2019, the Company sold an aggregate of 71,369 common shares under the August 2019 ATM Program at an average price of approximately $2.96 per common share for gross proceeds of approximately $0.2 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of the placement agent and legal fees in the aggregate amount of approximately $7,500.

**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**

Our mission is to develop first-in-class biological therapies for the treatment of diseases, with a focus on Duchenne muscular dystrophy, or DMD, and other rare disorders. Our executive offices are located at 8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211. Our telephone number is (310) 358-3200 and our Internet address is *www.capricor.com*.

***Drug Candidates***

**Our Product Candidates**

We currently have four drug candidates, two of which are in various stages of active development. Our current research and development efforts have been focused on CAP-1002 and CAP-2003. In 2018 we commenced enrollment of patients with DMD in a clinical trial of CAP-1002 called HOPE-2. CAP-1002 was also the subject of three previous clinical trials conducted by us. Recently, we decided to end the long-term follow-up which had been ongoing in our previously completed trials. CAP-1002 is also currently being investigated in two additional trials sponsored by Cedars-Sinai Medical Center, or CSMC, which are the REGRESS trial investigating heart failure with preserved ejection fraction and the ALPHA trial investigating pulmonary arterial hypertension. Although we are not the sponsor of these two trials, we are providing the investigational product for use in the trials. We are also evaluating CAP-2003 in pre-clinical studies for the treatment of various indications. CAP-1001 (autologous cardiosphere-derived cells, or CDCs) was the subject of the CSMC and The Johns Hopkins University, or JHU, sponsored Phase I CADUCEUS trial and is not in active development. Both CAP-1002 and CAP-1001 are derived from cardiospheres, or CSps, and we do not plan to develop CSps as a therapeutic.

**CAP-1002 for the Treatment of Duchenne Muscular Dystrophy:**

Based on our understanding of the mechanism of action of CAP-1002 which has been evaluated in pre-clinical and clinical studies of DMD, we believe that CAP-1002 has the potential to decrease inflammation and muscle degeneration while exerting positive effects on muscle regeneration, all of which may translate into patients retaining muscle function for a longer period of time. Data supporting peripheral intravenous route of administration of CAP-1002 in the DMD setting has been provided by pre-clinical mouse studies where CDCs, the active ingredient in CAP-1002, have been shown to increase exercise capacity and diaphragmatic function.

**Phase II HOPE-2 Clinical Trial**

HOPE-2 is a randomized, double-blind, placebo-controlled clinical trial which is being conducted at multiple sites located in the United States. To date, we have randomized 20 patients in our HOPE-2 clinical trial. The clinical trial was designed to evaluate the safety and efficacy of repeat, intravenous, or IV, doses of CAP-1002, in boys and young men with evidence of skeletal muscle impairment regardless of ambulatory status and who are on a stable regimen of systemic glucocorticoids. While there are many clinical initiatives in DMD, HOPE-2 is one of the very few to focus on non-ambulant patients. These boys and young men are looking to maintain what function they have in their arms and hands, and Capricor's previous study of a single intracoronary dose of CAP-1002 provided preliminary evidence of efficacy that CAP-1002 may be able to help DMD patients retain, or slow the loss of upper limb function.

The primary efficacy endpoint is the relative change in patients' abilities to perform manual tasks that relate to activities of daily living and are important to their quality of life. These abilities will be measured through the Performance of the Upper Limb, or PUL test. In the HOPE-2 study we are evaluating these through both the PUL 1.2 and 2.0 versions. HOPE-2 is focusing on the mid-level dimension of the PUL which assesses the ability to use muscles from the elbow to the hand, which are essential for operating wheelchairs and performing other daily functions. In HOPE-2, additional secondary and exploratory endpoints such as cardiac function, pulmonary function, quality of life and additional measures are included.

In July 2019, we reported interim top-line results from the HOPE-2 trial which showed that a pre-specified interim analysis performed on 6-month data showed meaningful results across several independent clinical measures.

In October 2019, we reported additional data from the interim analysis at the 24th Annual International Congress of the World Muscle Society. Data from a total of 20 patients was analyzed (12 placebo and 8 treated) at the 3- and 6-month time-point in the intent to treat (ITT) population. The late breaking podium presentation presented the top-line, 6-month results from the HOPE-2 clinical trial which showed meaningful results across several independent clinical measures which is summarized below. Although we have collected data from 5 treated patients at the 9-month timepoint, and 3 of which at the 12-month time-point, Capricor is not able to draw any conclusions at this time with respect to this data at this time.

**Skeletal Assessments**

To assess skeletal muscle function, investigators used the PUL, versions 1.2 and 2.0. The FDA has suggested the use of the updated PUL 2.0 version as the primary efficacy endpoint in support of a Biologics License Application, or BLA. Additional independent tests assessing grip strength showed improvements at 6 months and tests assessing tip to tip pinch strength showed positive results. We also expanded the skeletal assessment beyond the mid-level and evaluating patients' PUL "scores" to include the upper and distal dimensions.

**Skeletal Assessments at 3 and 6-month time-points (PUL 2.0) presented at World Muscle Society**

| **Time-point** | **3 months** | | | **6 months** | | |
|---|---|---|---|---|---|---|
| **Treatment** | **CAP-1002 n=8** | **Placebo n=10** | **p-value** | **CAP-1002 n=6** | **Placebo n=8** | **p-value** |
| Shoulder + Mid + Distal Level | 0.5 (1.69) | -1.2 (1.69) | 0.0549 | -0.3 (0.52) | -2.3 (1.49) | 0.0299 |
| Mid + Distal Level | 0.4 (1.30) | -0.4 (0.70) | 0.1035 | 0.2 (1.47) | -1.4 (0.92) | 0.0177 |
| Mid-level | 0.1 (0.99) | -0.4 (0.52) | 0.2202 | -0.2 (1.17) | -1.1 (0.99) | 0.0612 |

Mean Change from baseline (standard deviation) shown.
ITT (intent to treat) population shown
Comparisons treated vs. placebo using mixed model repeated ANOVA with covariates

**Pulmonary Assessments**

To assess pulmonary function, investigators measured several clinically relevant parameters. At 3 months, inspiratory flow reserve (absolute), a reflection of diaphragmatic strength, showed an improvement. Additionally, an improvement was observed at 3 months in peak expiratory flow (% predicted), another measure of diaphragmatic strength.

**Cardiac Assessments**

As reported from our July interim analysis, magnetic resonance imaging, MRI, was used to assess cardiac structure and function at 6 months. Positive trends were found in cardiac muscle function including systolic wall thickening and cardiac mass among those treated with CAP-1002 compared to placebo. Duchenne hearts atrophy progressively and have impaired systolic function. Improved mass and wall thickening suggest possible cardiac regeneration and functional improvement. These trends were consistent with the cardiac findings seen in the previously published HOPE-Duchenne study.

**Safety**

In late December 2018, Capricor put a voluntary hold on dosing after two patients in the HOPE trials had a serious adverse event in the form of an immediate immune reaction. The investigation suggested the patient may have developed hypersensitivity to something contained in the investigational product, including an excipient or inactive ingredient in the formulation. To reduce the risk of future adverse events, Capricor initiated a commonly used pre-medication strategy including oral steroids and antihistamines to prevent or mitigate potential immune reactions during the administration. Since the initiation of the pre-treatment regimen, approximately 40 infusions of investigational drug (CAP-1002 or placebo) have been administered to HOPE-2 patients with only one serious adverse event reported that required an overnight observation of the patient.

In June 2017, we had a meeting with the FDA to discuss potential clinical endpoints that could be used for registration strategies for CAP-1002 in the DMD indication. The minutes of the meeting indicated the FDA's willingness to accept Capricor's proposal to use the PUL test as the basis for the primary efficacy endpoint for clinical studies in support of a BLA. The PUL test is an outcome instrument that was specifically designed to assess upper limb function in ambulant and non-ambulant patients with DMD. In December 2018, we met again with the FDA as part of the expedited review afforded under the RMAT designation. The FDA grants the RMAT designation to investigational regenerative medicine therapies intended to treat a serious condition and for which preliminary clinical evidence indicates a potential to address unmet medical needs for that condition. During the RMAT discussion, which was reflected in subsequent meeting minutes issued by the FDA, Capricor asked whether the FDA would agree if HOPE-2 could serve as a registration study if the study provides evidence that CAP-1002 is safe and effective in treating Duchenne muscular dystrophy. The FDA advised Capricor to request an end of phase meeting after completion of the trial to determine whether HOPE-2 could serve as the registration study. The FDA also indicated its support for the use of the PUL 2.0 mid-level test, or the PUL 2.0, as the primary efficacy endpoint for HOPE-2. In addition, the agency stated that the trial would need to provide evidence of clinically meaningful changes in the PUL, as well as other evidence supportive of CAP-1002 efficacy for patients with advanced Duchenne muscular dystrophy, in order to potentially serve as a registration trial.

We recently had another meeting with the FDA to discuss, among other things, the results of the interim analysis of the HOPE-2 trial and our path forward with our DMD program. During the meeting, we proposed the possibility of accelerated approval. The FDA was not supportive of an accelerated approval pathway at this time. This notwithstanding, we intend to provide additional data from the HOPE-2 trial as it becomes available to continue this discussion. The FDA did, however, indicate its support of a Phase III trial of CAP-1002 for the treatment of DMD. Prior to the meeting, we had submitted a draft protocol for the Phase III trial which called for up to 70 patients. In addition, the FDA reiterated that as part of our RMAT designation, they are willing to work with us to further the clinical development of the therapy. Our further plans with respect to the clinical development of CAP-1002 in DMD will be based on the final guidance received from the FDA as well as other factors. We are now waiting on final minutes from the meeting. We also anticipate presenting the final 12-month data from the HOPE-2 study in the second quarter of 2020.

**Phase I/II HOPE-Duchenne Clinical Trial**

We have completed the randomized, controlled, multi-center Phase I/II HOPE-Duchenne clinical trial which was designed to evaluate the safety and exploratory efficacy of CAP-1002 in patients with cardiomyopathy associated with Duchenne muscular dystrophy, or DMD. Twenty-five patients were randomized in a 1:1 ratio to receive either CAP-1002 on top of usual care or usual care only. In patients receiving CAP-1002, 25 million cells were infused into each of their three main coronary arteries for a total dose of 75 million cells. It was a one-time treatment, and the last patient was infused in September 2016. Patients were observed over the course of 12 months. Efficacy was evaluated according to several exploratory outcome measures. This study was funded in part through a grant award, or the CIRM Award, from the California Institute for Regenerative Medicine, or CIRM. In January 2019, this study was published in the online issue of *Neurology*, the medical journal of the American Academy of Neurology.

We commenced the HOPE-Duchenne trial in February 2016 and completed enrollment in September 2016. In April 2017, we reported positive top-line results from a pre-specified six-month interim analysis of this study, which showed that CAP-1002 was generally safe and well-tolerated over the initial six-month follow-up period. The six-month results were presented at the 22$^{nd}$ Annual International Congress of the World Muscle Society in October 2017.

In exploratory efficacy analyses, observed changes from baseline to Month 6 significantly differed by treatment group for systolic thickening of the inferior wall of the heart as measured by MRI ($p=0.03$). In a post-hoc analysis of function of the mid- and distal-level upper limb in which a responder was defined as a patient who demonstrated a 10% improvement from baseline in score on the PUL test, CAP-1002 patients were more likely to be responders than patients in usual care ($p=0.045$) at Week 6. In addition, numerical results in some other cardiac and skeletal muscle measures, including cardiac scar ($p=0.09$), were consistent with a treatment effect although differences between treatment groups were not statistically significant. The observed clinical results appear to generally corroborate a large body of pre-clinical data from studies in DMD animal models.

We reported our 12-month data from the HOPE-Duchenne trial at a Late-Breaking Science session of the American Heart Association Scientific Sessions 2017.As shoulder function had already been lost in most of the HOPE participants, investigators used the combined mid-distal PUL subscales to assess changes in skeletal muscle function and found significant improvement in those treated with CAP-1002 in a defined post-hoc analysis. Among the lower-functioning patients, defined as patients with a baseline mid-distal PUL score of < 55 out of 58, investigators reported sustained or improved motor function at 12 months in 8 of 9 (89%) patients treated with CAP-1002 as compared to none (0%) of the usual care participants ($p=0.007$).

To assess cardiac structure and function, investigators used magnetic resonance imaging, or MRI. They found significant improvements in systolic thickening of the left ventricular wall among those patients treated with CAP-1002. Systolic wall thickening is the component of myocardial contraction ultimately responsible for ejection of blood from the left ventricle. Preservation or enhancement of systolic wall thickening may potentially be the result of the reversal of fibrosis.

In the inferior wall, they recorded a mean (SD) 31.2% (47.0%) increase in thickening six months after treatment and a mean 25.8% (46.7%) increase in thickening 12 months after treatment. In comparison, the usual care group showed a mean 8.8% (27.7%) decrease at six months and a mean 1.6% (37.9%) increase at 12 months in the systolic thickening of the inferior wall. The difference between the groups in absolute change from baseline to six months achieved statistical significance (p=0.04) and trended in favor of CAP-1002 treatment group (p=0.09) from baseline to 12 months.

Investigators also found that scarring of the heart muscle among those treated with CAP-1002 decreased relative to the control group. Progressive cardiac scarring eventually impairs the heart's pumping ability and is currently the leading cause of death in Duchenne muscular dystrophy. At the 12-month follow-up, those treated with CAP-1002 had a mean (SD) 7.1% (10.3%) reduction in scar size, in contrast to a mean 4.8% (22.3%) increase in scar size in the usual care group, a difference that achieved statistical significance using non-parametric analysis to account for outliers (p=0.03).

CAP-1002 was generally safe and well-tolerated in the HOPE-Duchenne trial. There was no significant difference in the incidence of treatment-emergent adverse events in either group. There were no early study discontinuations due to adverse events.

Additionally, in 2018 we conducted an open-label extension of the HOPE-Duchenne trial, or HOPE-OLE, where 8 patients who were randomized into the control group of the HOPE-Duchenne trial were given two doses of CAP-1002. We have completed enrollment and treatment of the patients in the HOPE-OLE trial. In January 2019, we entered into an Amendment to the CIRM Notice of Award pursuant to which CIRM allowed us to use excess funds from our grant award to fund, in part, certain activities associated with HOPE-OLE.

**Regulatory Designations for CAP-1002 for the treatment of DMD**

In April 2015, the FDA granted Orphan Drug Designation to CAP-1002 for the treatment of DMD. Orphan Drug Designation is granted by the FDA's Office of Orphan Drug Products to drugs intended to treat a rare disease or condition affecting fewer than 200,000 people in the United States or a disease or condition that affects more than 200,000 people in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. This designation confers special incentives to the drug developer, including tax credits on the clinical development costs and prescription drug user fee waivers and may allow for a seven-year period of market exclusivity in the United States upon FDA approval.

In July 2017, the FDA granted Rare Pediatric Disease Designation to CAP-1002 for the treatment of DMD. The FDA defines a "rare pediatric disease" as a serious or life-threatening disease affecting individuals primarily aged from birth to 18 years and that affects fewer than 200,000 individuals in the United States. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, upon the approval of a qualifying New Drug Application, or NDA, or BLA for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for a Rare Pediatric Disease Priority Review Voucher that can be used to obtain priority review for a subsequent NDA or BLA. The Priority Review Voucher may be sold or transferred an unlimited number of times.

In February 2018, we were notified by the FDA Office of Tissues and Advanced Therapies, that we were granted the Regenerative Medicine Advanced Therapy, or RMAT, designation for CAP-1002 for the treatment of DMD. The FDA grants the RMAT designation to regenerative medicine therapies intended to treat a serious condition and for which preliminary clinical evidence indicates a potential to address unmet medical needs for that condition. The RMAT designation makes therapies eligible for the same actions to expedite the development and review of a marketing application that are available to drugs that receive breakthrough therapy designation – including increased meeting opportunities, early interactions to discuss any potential surrogate or intermediate endpoints and the potential to support accelerated approval. CAP-1002 is one of the few therapies currently in development to help non-ambulant patients with Duchenne muscular dystrophy. To receive the RMAT designation, we submitted data from the HOPE-Duchenne Trial.

**CAP-1002 for the Treatment of Cardiac Conditions:**

In previous years, we completed several trials investigating the use of CAP-1002 for the treatment of various cardiac conditions, including heart failure (the DYNAMIC Trial) and post MI with cardiac dysfunction (ALLSTAR). Because of our decision to focus our efforts on DMD, we have decided not to pursue those indications at this time, nor do we have any plans to continue with the development of these programs although we are continuing to evaluate certain cardiac measures in our HOPE-2 trial. We expect no further material expenses in connection with these programs.

**Investigator Sponsored Clinical Trials**

Capricor has agreed to provide cells for investigational purposes in two clinical trials sponsored by CSMC. These cells were developed as part of the Company's past research and development efforts. The first trial is known as "Regression of Fibrosis and Reversal of Diastolic Dysfunction in HFpEF Patients Treated with Allogeneic CDCs." Dr. Eduardo Marbán is the named principal investigator under the study. The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells." In both studies, Capricor is providing the necessary number of doses of cells and will receive a negotiated amount of monetary compensation which is estimated to be approximately $2.1 million over several years.

**CAP-2003**:

Extracellular vesicles, or EVs, including exosomes and microvesicles are nano-scale, membrane-enclosed vesicles, that are secreted by cells and contain characteristic lipids, proteins and RNA molecules, such as microRNAs. EVs act as messengers to regulate the functions of neighboring cells, and pre-clinical research has shown that exogenously-administered exosomes can direct or, in some cases, re-direct cellular activity, supporting their therapeutic potential agents or delivery vehicles. Their size, ease of crossing cell membranes, and ability to communicate in native cellular language makes them an exciting class of potential therapeutic agents.

CAP-2003 is comprised of exosomes secreted by CDCs which are shown to mediate many of the effects that are observed with the CDCs, including anti-inflammatory, pro-angiogenic, anti-apoptotic, and anti-fibrotic effects. We are currently conducting studies in pre-clinical models of various conditions to explore the possible therapeutic benefits that CAP-2003 may possess. It is unknown at this time when an IND will be submitted for any particular indication. Additionally, in pre-clinical studies, we are exploring the use of CAP-2003 as a potential vehicle for delivering therapies to targeted tissues in the human body.

In July 2018, we entered into a Cooperative Research and Development Agreement with the U.S. Army Institute of Surgical Research pursuant to which the parties agreed to cooperate in research and development on the evaluation of CAP-2003 for the treatment of trauma related injuries and conditions, which are now the third leading cause of death in the U.S.

*Inactive or Discontinued Product Candidates*

**CAP-1001**:

CAP-1001 consists of autologous CDCs. This product candidate was evaluated in the randomized, double-blind, placebo-controlled Phase I CADUCEUS clinical trial in patients who had recently experienced an MI. The study was sponsored and conducted by CSMC in collaboration with JHU. At present, there is no plan for another clinical trial for CAP-1001.

**CSps**:

CSps are a 3D micro-tissue from which CDCs are derived, and have shown significant healing effects in pre-clinical models of heart failure. At present there is no plan to develop CSps as a therapeutic agent.

**Financial Operations Overview**

We have no commercial product sales to date and will not have the ability to generate any commercial product revenue until after we have received approval from the FDA or equivalent foreign regulatory bodies to begin selling our pharmaceutical product candidates. Developing pharmaceutical products is a lengthy and very expensive process. Even if we obtain the capital necessary to continue the development of our product candidates, whether through a strategic transaction or otherwise, we do not expect to complete the development of a product candidate for several years, if ever. To date, most of our development expenses have related to our product candidates, consisting of CAP-1002, CAP-2003 and our former product candidate, Cenderitide. As we proceed with the clinical development of CAP-1002, and as we further develop CAP-2003 and other additional products, 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 the products and our clinical programs. Our major sources of working capital to date have been proceeds from private and public equity sales, grants received from the National Institutes of Health, or NIH, and the Department of Defense, or DoD, a payment from Janssen Biotech, Inc., or Janssen, and a loan and grant award from CIRM. While we pursue our pre-clinical and clinical programs, we continue to explore financing and other strategic alternatives with respect to the Company as well as one or more of our product candidates.

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs, supplies, clinical trial costs, patient treatment costs, rent for laboratories and manufacturing facilities, consulting fees, costs of personnel and supplies for manufacturing, costs of service providers for pre-clinical, clinical and manufacturing, and certain legal expenses resulting from intellectual property prosecution, stock compensation expense and other expenses relating to the design, development, testing and enhancement of our product candidates. Except for certain capitalized intangible assets, R&D costs are expensed as incurred.

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

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

**Results of Operations**

*Revenue*

*Grant Income.* Grant income for the three months ended September 30, 2019 and 2018 was approximately $0.1 million and $0.2 million, respectively. The decrease in grant income of approximately $0.1 million in the third quarter of 2019 as compared to the third quarter of 2018 is primarily due to the timing of grant activities. During the third quarter of 2018, we had both the DoD and NIH Grant Awards active whereas only the DoD Grant Award was active during the third quarter of 2019.

Grant income for the nine months ended September 30, 2019 and 2018 was approximately $0.4 million and $0.8 million, respectively. The decrease in grant income of approximately $0.4 million for the nine months ended September 30, 2019 as compared to the same period of 2018 is primarily due to the timing of grant activities.

*Miscellaneous Income.* Miscellaneous income for the three months ended September 30, 2019 and 2018 was approximately $41,000 and $47,000, respectively. The miscellaneous income was primarily related to providing cells for investigational purposes for clinical trials sponsored by CSMC, which began in the third quarter of 2017.

Miscellaneous income for the nine months ended September 30, 2019 and 2018 was approximately $0.4 million and $0.3 million, respectively. The difference of approximately $0.1 million is primarily related to the timing of enrollment with respect to these trials.

*Operating Expenses*

*General and Administrative Expenses.* G&A expenses for the three months ended September 30, 2019 and 2018 were approximately $0.9 million and $1.3 million, respectively. The decrease of approximately $0.4 million in G&A expenses in the third quarter of 2019 compared to the same period of 2018 is primarily attributable to a decrease in stock-based compensation expense along with a reduction in headcount and other general expenses including investor relations expenses.

G&A expenses for the nine months ended September 30, 2019 and 2018 were approximately $2.7 million and $3.8 million, respectively. The decrease of approximately $1.1 million in G&A expenses in the first nine months of 2019 compared to the same period of 2018 is primarily attributable to a decrease in stock-based compensation expense along with a reduction in headcount and other general expenses including investor relations and legal expenses.

*Research and Development Expenses*. R&D expenses for the three months ended September 30, 2019 and 2018 were approximately $0.9 million and $3.1 million, respectively. The decrease of approximately $2.2 million in R&D expenses in the third quarter of 2019 compared to the same period of 2018 is primarily due to the timing of clinical development activities of CAP-1002 (HOPE-Duchenne, HOPE-2 and HOPE-OLE clinical trials). These activities resulted in a decrease in expenses of approximately $1.5 million. Furthermore, there was a decrease of approximately $0.7 million in research and development expenses related to CAP-1002 and CAP-2003 for the three months ended September 30, 2019 as compared to the same period in 2018. Additionally, there was a decrease of $0.1 million in stock based compensation expense in the third quarter of 2019 as compared to the same period of 2018.

R&D expenses for the nine months ended September 30, 2019 and 2018 were approximately $4.3 million and $9.2 million, respectively. The decrease of approximately $4.9 million in R&D expenses in the first nine months of 2019 compared to the same period of 2018 is primarily due to the timing of clinical development activities of CAP-1002 (HOPE-Duchenne, HOPE-2 and HOPE-OLE clinical trials). These activities resulted in a decrease of approximately $2.7 million in expenses. Furthermore, there was a decrease of approximately $1.6 million in research and development expenses related to CAP-1002 and CAP-2003 for the nine months ended September 30, 2019 as compared to the same period in 2018. Additionally, there was a decrease of $0.3 million in stock-based compensation expenses in the first nine months of 2019 as compared to the same period of 2018.

*Products Under Active Development*

*CAP-1002* – CAP-1002 is in its developmental stages. We expect to spend approximately $4.0 million to $5.0 million during 2019 on the clinical development of CAP-1002, which expenses are primarily related to our HOPE-2 clinical trial. These figures are largely dependent on the results of our discussions with the FDA, our ability to secure additional funding and various other factors.

*CAP-2003* – We expect to spend approximately $1.0 million to $2.0 million during 2019 on pre-clinical and other research expenses related to the CAP-2003 program, a portion of which will be offset by our grant award from the DoD. Capricor is currently engaged in pre-clinical testing of CAP-2003 to explore its therapeutic potential, including studies that could potentially enable an IND. We have received a grant from the DoD for up to approximately $2.4 million to be used towards the development of a scalable, commercially-ready process to manufacture CAP-2003. As of September 30, 2019, the Company has approximately $0.3 million available under this grant award, pursuant to the terms of the award.

*Products Not Under Active Development*

*CAP-1001* – In 2011, CSMC, in collaboration with JHU, completed the Phase I CADUCEUS trial. This study enrolled 25 patients who had suffered a heart attack within a mean of 65 days. 17 patients received CAP-1001 and 8 received standard of care. Twelve months after the study had completed, no measurable adverse effects occurred in the 17 patients who were treated with CAP-1001. 16 of the 17 treated patients showed a mean reduction of approximately 45% in scar mass and an increase in viable heart muscle one-year post heart attack. The 8 patients in the control group had no significant change in scar size. At present, there is no plan for an additional clinical trial of CAP-1001.

*CSps* – CSps are at the pre-clinical stage of development. At present, there is no plan for a clinical trial of CSps.

Our expenditures on current and future clinical development programs, particularly our CAP-1002 and CAP-2003 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. Further, we cannot predict with any significant degree of certainty the amount of time which will be required to complete our clinical trials, the costs of completing research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during manufacturing and clinical development and as a result of a variety of other factors, including:

- the number of trials and studies in a clinical program;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;
- the costs of manufacturing our product candidates; and
- the costs, requirements and timing of, and the ability to secure, regulatory approvals.

**Liquidity and Capital Resources**

The following table summarizes our liquidity and capital resources as of September 30, 2019 and December 31, 2018 and our net increase (decrease) in cash and cash equivalents for the nine months ended September 30, 2019 and 2018, 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, 2019** | **December 31, 2018** |
|---|---|---|
| Cash and cash equivalents | $ 6,828 | $ 4,259 |
| Working capital | $ 6,330 | $ 7,216 |
| Stockholders' equity | $ 3,570 | $ 4,616 |

| | **Nine months ended September 30,** | |
|---|---|---|
| **Cash flow data** | **2019** | **2018** |
| Cash provided by (used in): | | |
| Operating activities | $ (5,036) | $ (10,091) |
| Investing activities | 2,985 | 1,667 |
| Financing activities | 4,566 | 6,341 |
| Net increase (decrease) in cash and cash equivalents | $ 2,515 | $ (2,083) |

Our total cash and cash equivalents, not including restricted cash, as of September 30, 2019 was approximately $6.8 million compared to approximately $4.3 million as of December 31, 2018. The increase in cash and cash equivalents from December 31, 2018 as compared to September 30, 2019 is due to a reallocation of marketable securities to cash and cash equivalents of $3.0 million along with the net proceeds from the sale of common stock during the first nine months of 2019. Total marketable securities, consisting primarily of U.S. treasuries, were zero as of September 30, 2019, as compared to approximately $3.0 million as of December 31, 2018. As of September 30, 2019, we had approximately $4.3 million in total liabilities. As of September 30, 2019, we had approximately $6.3 million in net working capital. We had a net loss of approximately $1.6 million for the three months ended September 30, 2019 compared to a net loss of approximately $4.1 million in the same period of 2018. We incurred a net loss of approximately $6.2 million for the nine months ended September 30, 2019 compared to a net loss of approximately $11.9 million in the same period of 2018.

Cash used in operating activities was approximately $5.0 million and $10.1 million for the nine months ended September 30, 2019 and 2018, respectively. The difference of approximately $5.1 million in cash used in operating activities is primarily due to a decrease of $5.8 million in net loss for the nine months ended September 30, 2019 as compared to the same period in 2018. Furthermore, there was a change of approximately $0.4 million in accounts payable and accrued liabilities and a change of $0.5 million in prepaid expenses and other current assets for the nine months ended September 30, 2019 as compared to the same period in 2018. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, including if we expand our technology portfolio, engage in further research and development activities, and, in particular, conduct pre-clinical studies and clinical trials, we expect to continue incurring substantial losses, which will generate negative net cash flows from operating activities.

We had cash flow provided by investing activities of approximately $3.0 million and $1.7 million for the nine months ended September 30, 2019 and 2018, respectively. The increase in cash provided by investing activities for the nine months ended September 30, 2019 as compared to the same period of 2018 is primarily due to the net effect from purchases, sales, and maturities of marketable securities.

We had cash flow provided by financing activities of approximately $4.6 million and $6.3 million for the nine months ended September 30, 2019 and 2018, respectively. The decrease in cash provided by financing activities for the nine months ended September 30, 2019 as compared to the same period of 2018 is primarily due to the decrease in net proceeds received from the sale and issuance of common stock.

From inception through September 30, 2019, we financed our operations primarily through private and public sales of our equity securities, NIH and DoD grants, a payment from Janssen in connection with a Collaboration Agreement, a CIRM loan and a CIRM grant award. Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. As we have not generated any revenue from the commercial sale of our products to date, and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital in order to fund our immediate general corporate activities and, thereafter, to fund our research and development, including our long-term plans for clinical trials and new product development. We expect that if we are unable to raise additional capital, our current cash on hand will not be able to fund operations for a period of 12 months or more. We may seek to raise additional funds through various potential sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, complete our clinical trials or if such funds become available to us, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us.

Our estimates regarding the sufficiency of our financial resources are based on assumptions that may prove to be wrong. We may need to obtain additional funds sooner than planned or in greater amounts than we currently anticipate. 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, without limitation, the following:

- the progress of our research activities;
- the number and scope of our research programs;
- the progress and success of our pre-clinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- the costs of manufacturing our product candidates;
- our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;
- additional costs associated with maintaining licenses and insurance;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

***Financing Activities by the Company***

***August 2019 ATM Program.*** On August 29, 2019, the Company initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $1.95 million, or the August 2019 ATM Program, with the common stock to be distributed at the market prices prevailing at the time of sale. The August 2019 ATM Program was established under a Common Stock Sales Agreement, or the July 2019 Sales Agreement, with H.C. Wainwright & Co. LLC, or Wainwright, under which we may, from time to time, issue and sell shares of our common stock through Wainwright as sales agent. The July 2019 Sales Agreement provides that Wainwright will be entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold. All shares issued pursuant to the August 2019 ATM Program have been and will be issued pursuant to our shelf registration statement on Form S-3 (File No. 333-227955), which was initially filed with the Securities and Exchange Commission, or the SEC, on October 24, 2018, amended on July 17, 2019 and declared effective by the SEC on July 18, 2019. Since August 29, 2019 and through November 8, 2019, the Company has sold an aggregate of 360,316 common shares under the August 2019 ATM Program at an average price of approximately $3.07 per common share for gross proceeds of approximately $1.1 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of the placement agent and legal fees in the aggregate amount of approximately $0.1 million.

***July 2019 Common Stock Sales Agreement.*** On July 22, 2019, the Company initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $1.8 million, or the July 2019 ATM Program, with the common stock to be distributed at the market prices prevailing at the time of sale. The July 2019 ATM Program was established under the July 2019 Sales Agreement, which provides that Wainwright will be entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold. All shares issued pursuant to the July 2019 ATM Program were issued pursuant to our shelf registration statement on Form S-3 (File No. 333-227955), which was initially filed with the SEC on October 24, 2018, amended on July 17, 2019 and declared effective by the SEC on July 18, 2019. As of the expiration of the July 2019 ATM Program, the Company sold an aggregate of 418,450 common shares under the July 2019 ATM Program at an average price of approximately $4.30 per common share for gross proceeds of approximately $1.8 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of the placement agent and legal fees in the aggregate amount of approximately $0.1 million.

***October 2017 Common Stock Sales Agreement.*** On October 19, 2017, the Company entered into a Common Stock Sales Agreement, or the October 2017 Sales Agreement, with Wainwright, under which it could, from time to time, issue and sell shares of our common stock through Wainwright as sales agent in an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $14.0 million, or the October 2017 ATM Program. The common stock was distributed at the market prices prevailing at the time of sale. The October 2017 Sales Agreement provided that Wainwright would be entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold. All shares issued pursuant to the October 2017 ATM Program were issued pursuant to our shelf registration statement on Form S-3 (File No. 333-207149), which was initially filed with the SEC on September 28, 2015 and declared effective by the SEC on October 26, 2015. As of the expiration of the October 2017 ATM Program on April 23, 2019, the Company sold an aggregate of 899,233 common shares at an average price of approximately $13.04 per common share for gross proceeds of approximately $11.7 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of the placement agent and legal fees in the aggregate amount of approximately $0.4 million.

***Financing Activities by Capricor, Inc.***

***CIRM Grant Award***

On June 16, 2016, Capricor entered into the CIRM Award with CIRM in the amount of approximately $3.4 million to fund, in part, Capricor's Phase I/II HOPE-Duchenne clinical trial investigating CAP-1002 for the treatment of Duchenne muscular dystrophy-associated cardiomyopathy. Pursuant to terms of the CIRM Award, the disbursements were tied to the achievement of specified operational milestones. If CIRM determines, in its sole discretion, that Capricor has not complied with the terms and conditions of the CIRM Award, CIRM may suspend or permanently cease disbursements or pursue other remedies as allowed by law. In addition, the terms of the CIRM Award include a co-funding requirement pursuant to which Capricor is required to spend approximately $2.3 million of its own capital to fund the CIRM funded research project. If Capricor fails to satisfy its co-funding requirement, the amount of the CIRM Award may be proportionately reduced. The CIRM Award is further subject to the conditions and requirements set forth in the CIRM Grants Administration Policy for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, California Code of Regulations (CCR) Sections 100600-100612, and the sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from the CIRM funded research as set forth in Title 17, CCR Section 100608. The maximum royalty on net commercial revenue that Capricor may be required to pay to CIRM is equal to nine times the total amount awarded and paid to Capricor.

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

On August 8, 2017, Capricor entered into an Amendment to the CIRM Notice of Award pursuant to which CIRM approved Capricor's request to use the remaining estimated project funds of the CIRM Award for technology transfer activities in support of the manufacture of CAP-1002 to a designated contract manufacturing organization ("CMO") to help enable Capricor to offer access to CAP-1002 to patients from the control arm of the HOPE-Duchenne trial via an open-label extension protocol. On September 7, 2018, Capricor entered into an Amendment to the CIRM Notice of Award pursuant to which CIRM added an additional operational milestone which would be satisfied by completion of certain activities related to technology transfer. On January 23, 2019, Capricor entered into an Amendment to the CIRM Notice of Award pursuant to which CIRM added an additional operational milestone which would be satisfied by completion of certain activities related to the HOPE-OLE clinical trial.

In 2016, Capricor received $3.1 million under the terms of the CIRM Award. In September 2017, Capricor completed the second operational milestone tied to the last patient completing one year of follow-up, for which approximately $0.3 million was received by Capricor in November 2017. As of September 30, 2019, Capricor's liability balance for the CIRM Award was $3.4 million. In June 2019, Capricor completed all milestones associated with the CIRM Award and expended all funds received. In the third quarter of 2019, Capricor completed all final close-out documentation associated with this award.

***NIH Grant Award (HLHS)***

In September 2016, Capricor was approved for a grant from the NIH to study CAP-2003 (cardiosphere-derived cell exosomes) for hypoplastic left heart syndrome (HLHS). Under the terms of the NIH grant, disbursements will be made to Capricor in an amount up to approximately $4.2 million, subject to annual and quarterly reporting requirements as well as completion of the study objectives. As of June 30, 2019, approximately $0.7 million has been incurred under the terms of the NIH grant award. In the second quarter of 2019, the award was closed and all filings completed with no additional expenses expected to be incurred.

***U.S. Department of Defense Grant Award***

In September 2016, Capricor was approved for a grant award from the Department of Defense in the amount of approximately $2.4 million to be used toward developing a scalable, commercially-ready process to manufacture CAP-2003. Under the terms of the award, disbursements will be made to Capricor over a period of approximately three years, subject to annual and quarterly reporting requirements. The Company was granted a no-cost extension until September 29, 2020 to be able to continue to utilize these funds. As of September 30, 2019, approximately $2.1 million has been incurred under the terms of the award.

**Contractual Obligations and Commitments**

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

**Off-Balance Sheet Arrangements**

There were no off-balance sheet arrangements as described by Item 303(a)(4) of Regulation S-K as of September 30, 2019.

**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.

***Revenue Recognition***

For contracts completed as of December 31, 2017, revenue was recognized in accordance with ASC 605 and other standards which have been superseded for subsequent fiscal years. The Company applied ASU 606 using the modified retrospective approach for all contracts in process as of January 1, 2018.

*Grant Income*

The determination as to when income is earned is dependent on the language in each specific grant. Generally, we recognize grant income in the period in which the expense is incurred for those expenses that are deemed reimbursable under the terms of the grant. Grant income is due upon submission of reimbursement request. The transaction price varies for grant income based on the expenses incurred under the awards.

*Miscellaneous Income*

Revenue is recognized in connection with the delivery of doses which were developed as part of our past R&D efforts. Income is recorded when the Company has satisfied the obligations as identified in the contracts with the customer. Miscellaneous income is due upon billing. Miscellaneous income is based on contracts with fixed transaction prices.

***CIRM Grant Award***

Capricor accounts for the disbursements under its CIRM Award as long-term liabilities. Capricor recognizes the CIRM grant disbursements as a liability as the principal is disbursed rather than recognizing the full amount of the grant award. After completing the CIRM funded research project and after the award period end date, Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and the stage of development at the time the election is made. 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 pre-clinical, clinical and manufacturing, and certain legal expenses resulting from intellectual property prosecution, stock compensation expense and other expenses relating to the design, development, testing and enhancement of our product candidates. Except for certain capitalized intangible assets, R&D costs are expensed as incurred.

Our cost accruals for clinical trials and other R&D activities are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and contract research organizations, or CROs, clinical study sites, laboratories, consultants or other clinical trial vendors that perform activities in connection with a trial. Related contracts vary significantly in length and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of fixed, variable and capped amounts. Activity levels are monitored through close communication with the CROs and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CRO and significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter for each individual trial. These estimates are reviewed and discussed with the CRO or vendor as necessary, and are included in R&D expenses for the related period. For clinical study sites which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrollment in each quarter. All estimates may differ significantly from the actual amount subsequently invoiced, which may occur several months after the related services were performed.

In the normal course of business, we contract with third parties to perform various R&D activities in the on-going development of our product candidates. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of the accrual policy is to match the recording of expenses in the financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials and other R&D activities are recognized based on our estimates of the degree of completion of the event or events specified in the applicable contract.

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

***Stock-Based Compensation***

Our results include non-cash compensation expense as a result of the issuance of stock, stock options and warrants, as applicable. We have issued stock options to employees, directors and consultants under our three stock option plans: (i) the 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan (which superseded the 2006 Stock Option Plan), and (iii) the 2012 Non-Employee Director Stock Option 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, the risk-free interest rate and the estimated rate of forfeitures of unvested stock options.

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. Historically, the Company periodically re-measured the fair value for non-qualified option grants recording an expense over the applicable vesting periods. However, in the third quarter of 2018, the Company early adopted ASU 2018-07. The Company calculates the fair value for non-qualified options as of the date of grant and expenses over the applicable vesting periods.

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

***Restricted Cash***

Prior to March 31, 2019, restricted cash represents funds received under the CIRM Award. Restricted cash funds are to be allocated to the research costs as incurred. Generally, a reduction of restricted cash occurs when the Company deems certain costs are attributable to the respective award. The Company fully utilized the CIRM Award in June 2019.

In April 2019, the Company entered into a letter of credit for $232,803 as a security deposit for its lease agreement for corporate office space. The Company is required to maintain this deposit for the duration of the lease term. The amount of this security deposit is included in our restricted cash for the period ended September 30, 2019.

***Recently Issued or Newly Adopted Accounting Pronouncements***

In February 2016, the Financial Accounting Standards Board, FASB, issued ASU 2016-02, *Leases (Topic 842)*, or ASU 2016-02*,* which supersedes existing guidance on accounting for leases in *Leases (Topic 840)* and issued additional clarification throughout 2018. Under the new guidance, a lessee should recognize assets and liabilities that arise from its leases and disclose qualitative and quantitative information about its leasing arrangements. The Company elected the optional transition method to apply the standard as of January 1, 2019 as the effective date and therefore, did not apply the standard to comparative periods. The Company did not apply the recognition requirements to short-term leases and recognized those lease payments in the Consolidated Statements of Operations on a straight-line basis over the lease term. The Company also elected the available package of practical expedients in transition which allowed us to not re-assess whether existing or expired arrangements contain a lease, the lease classification of existing or expired leases, or whether previous initial direct costs would qualify for capitalization under the new lease standard. The adoption of this update did not have a material impact on the Company's financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The Company early adopted ASU 2018-07 and all subsequent updates related to this topic on a prospective basis effective July 1, 2018. The adoption of this update did not have a material impact on the Company's financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808):* clarifying the interaction between Topic 808 and Topic 606. The amendments in the update clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account; adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 when an entity is assessing whether the collaborative arrangement or a party of the arrangement is within the scope of Topic 606; requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The amendments for this update are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of the new guidance on our consolidated financial statements.

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, 2019, the fair value of our cash, cash equivalents, including restricted cash, was approximately $7.1 million. Additionally, as of September 30, 2019, Capricor's portfolio was classified as cash and cash equivalents, which consisted primarily of money market funds and bank money market, which included short term U.S. treasuries, bank savings and checking accounts.

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

**Item 4. Controls and Procedures.**

We have adopted and maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that controls and procedures, no matter how well designed and operated, cannot provide absolute assurance of achieving the desired control objectives.

As required by Rules 13a-15(b) and 15d-15(b) of the Securities Exchange Act of 1934, as amended, we carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level.

***Changes in Internal Controls over Financial Reporting***

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II — OTHER INFORMATION

### Item 1. Legal Proceedings.

We are not involved in any material pending legal proceedings and are not aware of any material threatened legal proceedings against us.

### Item 1A. Risk Factors.

Part 1, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on March 29, 2019, and as amended by our Amendment No. 1 to Annual Report on Form 10-K/A filed with the SEC on April 1, 2019, 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. Except as set forth below, 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, 2018, as filed with the SEC on March 29, 2019, and as amended by our Amendment No. 1 to Annual Report on Form 10-K/A filed with the SEC on April 1, 2019.

#### Risks Related to Our Common Stock

***If we do not regain and maintain compliance with Nasdaq Listing Rule 5550(b)(1), our common stock may be subject to delisting from the Nasdaq Capital Market.***

On August 14, 2019, we received a written notice, or the Deficiency Notice, from Nasdaq indicating that we were not in compliance with Nasdaq Listing Rule 5550(b)(1), or Rule 5550(b)(1), as our stockholders' equity, as reported on our Quarterly Report on Form 10-Q for the period ended June 30, 2019, was below $2.5 million, which is the minimum stockholders' equity required for compliance with Rule 5550(b)(1).

Pursuant to the Deficiency Notice, we were granted a 45-calendar day compliance period, or until September 30, 2019, to submit a plan to regain and maintain compliance with Rule 5550(b)(1), or a Compliance Plan. We submitted a Compliance Plan to Nasdaq prior to the expiration of the 45-calendar day compliance period setting forth potential courses of action designed to regain and maintain compliance with Rule 5550(b)(1), and Nasdaq subsequently requested that we provide an update to our Compliance Plan no later than November 8, 2019, which date was subsequently extended until November 14, 2019, to enable us to file this Quarterly Report on Form 10-Q prior to providing such update. While our stockholders' equity reported in this Quarterly Report on Form 10-Q is above the $2.5 million minimum required for compliance with Rule 5550(b)(1), Nasdaq will also consider whether we are likely to maintain compliance with the minimum stockholders' equity requirement prior to determining that we have regained compliance with Rule 5550(b)(1). Accordingly, there can be no assurance that we will regain compliance with Rule 5550(b)(1).

Failure to regain compliance with Rule 5550(b)(1) could result in our common stock being delisted from Nasdaq, in which case our common stock would likely trade only on the over-the-counter market, or the OTC. If our common stock were to trade on the OTC, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and it may be difficult to attract security analysts' coverage. In addition, in the event our common stock is delisted, broker-dealers transacting in our common stock would be subject to certain additional regulatory burdens, which may discourage them from effecting transactions in our common stock, thus further limiting the liquidity of our common stock and potentially resulting in lower prices and larger spreads in the bid and ask prices for our common stock.

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

Not applicable.

### Item 3. Defaults Upon Senior Securities.

Not applicable.

### Item 4. Mine Safety Disclosures.

Not applicable.

### Item 5. Other Information.

None.

**Item 6. Exhibits.**

| | |
|---|---|
| 2.1 | Agreement and Plan of Merger, dated as of August 15, 2007, by and among SMI Products, Inc., Nile Merger Sub, Inc. and Nile Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on August 17, 2007). |
| 2.2 | Agreement and Plan of Merger and Reorganization, dated as of July 7, 2013, by and among Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 9, 2013). |
| 2.3 | First Amendment to Agreement and Plan of Merger and Reorganization, dated as of September 27, 2013, by and between Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on October 3, 2013). |
| 3.1 | Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 9, 2007). |
| 3.2 | Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 26, 2013). |
| 3.3 | Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 4, 2019). |
| 3.4 | 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). |
| 10.1 | Common Stock Sales Agreement, dated July 22, 2019, between Capricor Therapeutics, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 22, 2019). |
| 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, 2019 formatted in eXtensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity, (iv) Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.* |

* Filed herewith.

**SIGNATURES**

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

**CAPRICOR THERAPEUTICS, INC.**

Date: November 8, 2019

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

Date: November 8, 2019

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

**Exhibit 31.1**

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER**

I, Linda Marbán, Ph.D., certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2019

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

**Exhibit 31.2**

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER**

I, Anthony J. Bergmann, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2019

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

**Exhibit 32.1**

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

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Linda Marbán, Ph.D., the Principal Executive Officer of Capricor Therapeutics, Inc. (the "**Company**"), hereby certifies, to her knowledge, that:

(1) the Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2019 (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 8, 2019

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

**Exhibit 32.2**

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

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

(1) the Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2019 (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 8, 2019

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