

CAPRICOR THERAPEUTICS, INC.

Form 10-Q

November 14, 2018

**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, 2018**

**or**

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

**Commission File Number: 001-34058**

**CAPRICOR THERAPEUTICS, INC.**

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

**Delaware**

**(State or other jurisdiction of  
incorporation or organization)**

**88-0363465**

**(I.R.S. Employer Identification No.)**

**8840 Wilshire Blvd., 2<sup>nd</sup> Floor, Beverly Hills, California 90211**

**(Address of principal executive offices including zip code)**

**(310) 358-3200**

**(Registrant's telephone number, including area code)**

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

| <b>Title of Each Class</b>                | <b>Name of Each Exchange on Which Registered</b> |
|---|--|
| Common Stock, par value \$0.001 per share | The Nasdaq Capital Market                        |

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

**None**

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 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

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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

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

As of November 14, 2018, there were 31,067,359 shares of the registrant's common stock, par value \$0.001 per share, issued and outstanding.

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## Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “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 or 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,<br>2018<br>(unaudited) | December 31,<br>2017 |
|---|--------------------------------------|----------------------|
| <b>ASSETS</b>   |                                      |                      |
| <b>CURRENT ASSETS</b>   |                                      |                      |
| Cash and cash equivalents   | \$ 4,377,797                         | \$ 6,140,135         |
| Marketable securities   | 5,994,120                            | 7,984,800            |
| Restricted cash   | 421,718                              | 742,002              |
| Grant receivable  | 172,589                              | 344,575              |
| Prepaid expenses and other current assets   | 426,422                              | 501,164              |
| <b>TOTAL CURRENT ASSETS</b>   | <b>11,392,646</b>                    | <b>15,712,676</b>    |
| <b>PROPERTY AND EQUIPMENT, net</b>  | <b>622,277</b>                       | <b>372,096</b>       |
| <b>OTHER ASSETS</b>   |                                      |                      |
| Intangible assets, net of accumulated amortization of \$199,091 and \$166,634, respectively | 60,591                               | 93,048               |
| Other assets  | 157,302                              | 95,969               |
| <b>TOTAL ASSETS</b>   | <b>\$ 12,232,816</b>                 | <b>\$ 16,273,789</b> |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                                      |                      |
| <b>CURRENT LIABILITIES</b>  |                                      |                      |
| Accounts payable and accrued expenses   | \$ 1,743,788                         | \$ 1,496,251         |
| Accounts payable and accrued expenses, related party  | 132,347                              | 174,424              |
| <b>TOTAL CURRENT LIABILITIES</b>  | <b>1,876,135</b>                     | <b>1,670,675</b>     |
| <b>LONG-TERM LIABILITIES</b>  |                                      |                      |
| CIRM liability  | 3,376,259                            | 3,376,259            |
| <b>TOTAL LONG-TERM LIABILITIES</b>  | <b>3,376,259</b>                     | <b>3,376,259</b>     |



|  |               |                 |
|--|---------------|-----------------|
| TOTAL LIABILITIES  | 5,252,394     | 5,046,934       |
| COMMITMENTS AND CONTINGENCIES (NOTE 7)   |               |                 |
| 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, 30,748,872 and 26,270,491 shares issued and outstanding, respectively | 30,749        | 26,271          |
| Additional paid-in capital   | 70,408,501    | 62,736,783      |
| Accumulated other comprehensive income   | 20,207        | 11,620          |
| Accumulated deficit  | (63,479,035   | ) (51,547,819 ) |
| TOTAL STOCKHOLDERS' EQUITY   | 6,980,422     | 11,226,855      |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY   | \$ 12,232,816 | \$ 16,273,789   |

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<br>30, |                        | Nine months ended September<br>30, |                        |
|--|-------------------------------------|------------------------|------------------------------------|------------------------|
|  | <b>2018</b>                         | <b>2017</b>            | <b>2018</b>                        | <b>2017</b>            |
| <b>INCOME</b>  |                                     |                        |                                    |                        |
| Collaboration income                                 | \$ -                                | \$ -                   | \$ -                               | \$ 1,367,186           |
| Grant income   | 172,589                             | 260,771                | 766,641                            | 770,855                |
| Other income   | 46,658                              | 52,500                 | 256,633                            | 52,500                 |
| <b>TOTAL INCOME</b>                                  | <b>219,247</b>                      | <b>313,271</b>         | <b>1,023,274</b>                   | <b>2,190,541</b>       |
| <b>OPERATING EXPENSES</b>                            |                                     |                        |                                    |                        |
| Research and development                             | 3,131,999                           | 1,862,369              | 9,217,423                          | 8,247,700              |
| General and administrative                           | 1,259,180                           | 1,088,635              | 3,826,972                          | 3,524,815              |
| <b>TOTAL OPERATING EXPENSES</b>                      | <b>4,391,179</b>                    | <b>2,951,004</b>       | <b>13,044,395</b>                  | <b>11,772,515</b>      |
| <b>LOSS FROM OPERATIONS</b>                          | <b>(4,171,932 )</b>                 | <b>(2,637,733 )</b>    | <b>(12,021,121 )</b>               | <b>(9,581,974 )</b>    |
| <b>OTHER INCOME (EXPENSE)</b>                        |                                     |                        |                                    |                        |
| Investment income                                    | 35,792                              | 10,393                 | 89,905                             | 26,726                 |
| Interest expense                                     | -                                   | (107,653 )             | -                                  | (318,500 )             |
| <b>TOTAL OTHER INCOME (EXPENSE)</b>                  | <b>35,792</b>                       | <b>(97,260 )</b>       | <b>89,905</b>                      | <b>(291,774 )</b>      |
| <b>NET LOSS</b>                                      | <b>(4,136,140 )</b>                 | <b>(2,734,993 )</b>    | <b>(11,931,216 )</b>               | <b>(9,873,748 )</b>    |
| <b>OTHER COMPREHENSIVE INCOME<br/>(LOSS)</b>         |                                     |                        |                                    |                        |
| Net unrealized gain on marketable securities         | 1,922                               | 1,276                  | 8,587                              | 5,069                  |
| <b>COMPREHENSIVE LOSS</b>                            | <b>\$ (4,134,218 )</b>              | <b>\$ (2,733,717 )</b> | <b>\$ (11,922,629 )</b>            | <b>\$ (9,868,679 )</b> |
| Net loss per share, basic and diluted                | \$ (0.14 )                          | \$ (0.12 )             | \$ (0.41 )                         | \$ (0.44 )             |
| Weighted average number of shares, basic and diluted | 30,610,064                          | 23,378,141             | 28,862,665                         | 22,311,369             |

See accompanying notes to the unaudited condensed consolidated financial statements.



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

|  | COMMON STOCK<br>SHARES | COMMON STOCK<br>AMOUNT | ADDITIONAL<br>PAID-<br>IN CAPITAL | OTHER<br>COMPREHENSIVE<br>INCOME | ACCUMULATED<br>DEFICIT | TOTAL<br>STOCKHOLDERS'<br>EQUITY |
|--|------------------------|------------------------|-----------------------------------|----------------------------------|------------------------|----------------------------------|
| Balance at December 31, 2017             | 26,270,491             | \$ 26,271              | \$ 62,736,783                     | \$ 11,620                        | \$(51,547,819 )        | \$ 11,226,855                    |
| Issuance of common stock, net of fees    | 4,073,160              | 4,073                  | 6,198,204                         | -                                | -                      | 6,202,277                        |
| Stock-based compensation                 | 29,166                 | 29                     | 1,334,750                         | -                                | -                      | 1,334,779                        |
| Unrealized gain on marketable securities | -                      | -                      | -                                 | 8,587                            | -                      | 8,587                            |
| Stock options exercised                  | 376,055                | 376                    | 138,764                           | -                                | -                      | 139,140                          |
| Net loss                                 | -                      | -                      | -                                 | -                                | (11,931,216 )          | (11,931,216 )                    |
| Balance at September 30, 2018            | 30,748,872             | \$ 30,749              | \$ 70,408,501                     | \$ 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, |                      |
|---|---------------------------------|----------------------|
|   | 2018                            | 2017                 |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                                  |                                 |                      |
| Net loss  | \$ (11,931,216 )                | \$ (9,873,748 )      |
| Adjustments to reconcile net loss to net cash used in operating activities:   |                                 |                      |
| Depreciation and amortization   | 114,357                         | 109,595              |
| Stock-based compensation  | 1,334,779                       | 1,297,362            |
| Change in assets - (increase) decrease:                                       |                                 |                      |
| Receivables   | 171,986                         | (37,436 )            |
| Prepaid expenses and other current assets                                     | 74,742                          | 152,614              |
| Other assets  | (61,333 )                       | 30                   |
| Change in liabilities - increase (decrease):                                  |                                 |                      |
| Accounts payable and accrued expenses   | 247,537                         | (1,773,999 )         |
| Accounts payable and accrued expenses, related party                          | (42,077 )                       | (389,314 )           |
| Accrued interest  | -                               | 318,500              |
| Deferred revenue  | -                               | (1,367,186 )         |
| <b>NET CASH USED IN OPERATING ACTIVITIES</b>                                  | <b>(10,091,225 )</b>            | <b>(11,563,582 )</b> |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                                  |                                 |                      |
| Purchase of marketable securities   | (15,000,733 )                   | (11,002,271 )        |
| Proceeds from sales and maturities of marketable securities                   | 17,000,000                      | 19,000,000           |
| Purchases of property and equipment   | (332,081 )                      | (32,185 )            |
| <b>NET CASH PROVIDED BY INVESTING ACTIVITIES</b>                              | <b>1,667,186</b>                | <b>7,965,544</b>     |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                                  |                                 |                      |
| Net proceeds from sale of common stock  | 6,202,277                       | 8,303,697            |
| Proceeds from loan payable  | -                               | 250,000              |
| Proceeds from stock options   | 139,140                         | -                    |
| <b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>                              | <b>6,341,417</b>                | <b>8,553,697</b>     |
| <b>NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH</b> | <b>(2,082,622 )</b>             | <b>4,955,659</b>     |
| Cash, cash equivalents, and restricted cash balance at beginning of period    | 6,882,137                       | 4,551,603            |
| Cash, cash equivalents, and restricted cash balance at end of period          | \$ 4,799,515                    | \$ 9,507,262         |

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 22, 2018, from which the December 31, 2017 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, 2018.

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, 2018 were approximately \$10.4 million, compared to approximately \$14.1 million as of December 31, 2017. On October 19, 2017, the Company entered into a Common Stock Sales Agreement (the “October Sales Agreement”) with Wainwright to create an at-the-market equity program under which the Company from time to time may offer and sell shares of its common stock, par value \$0.001 per share, having an aggregate offering price of up to \$14.0 million (the “October 2017 ATM Program”) through Wainwright, as sales agent. As of November 13, 2018, the Company has sold an aggregate of 5,417,750 common shares under the October 2017 ATM Program at an average price of approximately \$1.75 per common share for net proceeds of approximately \$9.2 million (see Note 3 – “Stockholders’ Equity” and Note 10 – “Subsequent Events”). Furthermore, as of November 13, 2018, the Company has approximately \$4.5 million available for future issuance under the October 2017 ATM Program until it expires in accordance with its terms.

The Company has been awarded various grant and loan awards, which fund, in part, various pre-clinical and clinical activities (see Note 2 – “Loan Payable” and Note 6 – “Government Grant Awards”). As of September 30, 2018, the Company has up to approximately \$4.4 million available under these grants and awards for disbursement, pursuant to the terms of each of the respective awards.



**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

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

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

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

- the timing and costs associated with 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 operating plan, the Company believes it has sufficient cash to fund operations into the second quarter of 2019. If necessary, Capricor is able to make certain operational adjustments to further reduce expenses by slowing down certain R&D efforts, decreasing headcount, and implementing further budget restrictions in order to preserve cash resources further. 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 plan to address its financial position may include potentially seeking additional financing primarily from, but not limited to, the sale and issuance of equity or debt securities, the licensing or sale of its technology and from government grants. The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The Company will require substantial additional capital to fund 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 or at all. 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 or curtail portions of its clinical trial programs. To the extent the Company issues additional equity securities, its existing stockholders could experience substantial dilution.

#### Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. 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 statement of cash flows.

**CAPRICOR THERAPEUTICS, INC.****Notes to CONDENSED CONSOLIDATED financial statements****(unaudited)****1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

|   | September 30,<br>2018 | September 30,<br>2017 |
|---|-----------------------|-----------------------|
| Cash and cash equivalents   | \$ 4,377,797          | \$ 8,897,087          |
| Restricted cash   | 421,718               | 610,175               |
| Total cash, cash equivalents, and restricted cash shown in the statements of cash flows | \$ 4,799,515          | \$ 9,507,262          |

During the year ended December 31, 2017, the Company had two awards from CIRM designated for specific use; a Loan Agreement with CIRM (the “CIRM Loan Agreement”) entered into on February 5, 2013 (see Note 2 – “Loan Payable”) in connection with the ALLSTAR Phase II clinical trial and the CIRM Award (see Note 6 – “Government Grant Awards”) related to the HOPE Phase I/II clinical trial. Restricted cash represents funds received under these awards which are to be allocated to the research costs as incurred. In December 2017, the Company abandoned the CIRM funded project, and as a result approximately \$15.7 million consisting of principal and accrued interest was forgiven under the CIRM Loan Agreement. All reporting obligations were completed in the first quarter of 2018 (see Note 2 - “Loan Payable”). Generally, a reduction of restricted cash occurs when the Company deems certain costs are attributable to the respective award. The restricted cash balance was approximately \$0.4 million and \$0.7 million as of September 30, 2018 and December 31, 2017, respectively, and is entirely related to the CIRM 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 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

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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 \$81,900 and \$73,034 for the nine months ended September 30, 2018 and 2017, respectively.

Property and equipment consisted of the following as of September 30, 2018 and December 31, 2017:

|                               | September 30,<br>2018 | December 31,<br>2017 |
|-------------------------------|-----------------------|----------------------|
| Furniture and fixtures        | \$ 46,709             | \$ 46,709            |
| Laboratory equipment          | 952,075               | 619,994              |
| Leasehold improvements        | 47,043                | 47,043               |
|                               | 1,045,827             | 713,746              |
| Less accumulated depreciation | (423,550 )            | (341,650 )           |
| Property and equipment, net   | \$ 622,277            | \$ 372,096           |

**CAPRICOR THERAPEUTICS, INC.****Notes to CONDENSED CONSOLIDATED financial statements****(unaudited)****1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**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 and \$36,562 for the nine months ended September 30, 2018 and 2017, respectively. A summary of future amortization expense as of September 30, 2018 is as follows:

| Years ended     | Amortization Expense |
|-----------------|----------------------|
| 2018 (3 months) | \$ 10,820            |
| 2019            | 43,276               |
| 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, 2018 and 2017.

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 granted in connection with the HOPE trial 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 6 - "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.

*Income from Collaborative Agreement*

Revenue from nonrefundable, up-front license or technology access payments under license and collaborative arrangements that are not dependent on any future performance by the Company is recognized when such amounts are earned. If the Company has continuing obligations to perform under the arrangement, such fees are recognized over the estimated period of the continuing performance obligation.

During 2017, the Company accounted for multiple element arrangements, such as license and development agreements in which a customer may purchase several deliverables, in accordance with FASB ASC Subtopic 605-25, *Multiple Element Arrangements*. For new or materially amended multiple element arrangements, the Company identified the deliverables at the inception of the arrangement and each deliverable within a multiple deliverable revenue arrangement was accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in the Company's control. The Company allocated revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, the Company determined the selling price for each deliverable using vendor-specific objective evidence ("VSOE") of selling price, if it exists, or third-party evidence ("TPE") of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, then the Company uses the best estimated selling price for that deliverable. Revenue allocated to each element was then recognized based on when the basic four revenue recognition criteria were met for each element.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

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

The Company determined that the deliverables under its Collaboration Agreement with Janssen (see Note 8 – “License Agreements”) did not meet the criteria to be considered separate accounting units for the purposes of revenue recognition. As a result, the Company recognized revenue from non-refundable, upfront fees ratably over the term of its performance under the agreement with Janssen. The upfront payments received, pending recognition as revenue, were recorded as deferred revenue and were classified as a short-term or long-term liability on the condensed consolidated balance sheets of the Company and amortized over the estimated period of performance. The Company periodically reviewed the estimated performance period of its contract based on the estimated progress of its project. As of June 30, 2017, the full amount of income has been recognized under the Janssen Agreement and the Janssen Agreement terminated.

*Other 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 9 – “Related Party Transactions”). Other income is due upon billing. Other income is based on contracts with fixed transaction prices.

Loan Payable

The Company accounted for the funds advanced under the CIRM Loan Agreement as a loan payable as the eventual repayment of the loan proceeds or forgiveness of the loan was contingent upon certain milestones being met and other conditions (see Note 2 – “Loan Payable”). On November 17, 2017, the Company gave notice to CIRM that it was electing to abandon the CIRM-funded project pursuant to the Loan Agreement and on December 11, 2017, Capricor and CIRM entered into Amendment No. 3 to the CIRM Notice of Loan Award whereby the total loan balance under the CIRM Loan Agreement has been forgiven by CIRM thereby terminating Capricor and the Company’s obligation to repay the loan balance.

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 condensed 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 FASB ASC 730-10, *Research and Development*. Research and development costs amounted to approximately \$3.1 million and \$1.9 million for the three months ended September 30, 2018 and 2017, respectively, and approximately \$9.2 million and \$8.2 million for the nine months ended September 30, 2018 and 2017, 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 \$4.1 million and \$2.7 million for the three months ended September 30, 2018 and 2017, respectively, and approximately \$11.9 million and \$9.9 million for the nine months ended September 30, 2018 and 2017, 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, 2018 and 2017, the Company's other comprehensive income was \$1,922 and \$1,276, respectively. For the nine months ended September 30, 2018 and 2017, the Company's other comprehensive income was \$8,587 and \$5,069, 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.



**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

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

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.

Earnings (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.

For the three and nine months ended September 30, 2018 and 2017, warrants and options to purchase 8,368,703 and 8,014,863 shares of common stock, respectively, have been excluded from the computation of potentially dilutive securities. Dilutive potential 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

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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:

| <b>Level</b> | <b>Input Definition:</b>   |
|--------------|--|
| 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:

|                       | September 30, 2018 |          |           |             |
|-----------------------|--------------------|----------|-----------|-------------|
|                       | Level I            | Level II | Level III | Total       |
| Marketable Securities | \$5,994,120        | \$ -     | \$ -      | \$5,994,120 |

|                       | December 31, 2017 |          |           |             |
|-----------------------|-------------------|----------|-----------|-------------|
|                       | Level I           | Level II | Level III | Total       |
| Marketable Securities | \$7,984,800       | \$ -     | \$ -      | \$7,984,800 |

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

(unaudited)

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

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 May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"). ASU 2014-09 amended the existing accounting standards for revenue recognition. ASU 2014-09 establishes principles for recognizing revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The Company adopted ASU 2014-09 and all subsequent updates related to this topic in the first quarter of 2018 using the modified retrospective approach. The adoption of this ASU was applied to only those contracts that were not completed upon the initial application. The adoption of this update did not have a material impact on the Company's financial statements.

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 generally requires all leases to be recognized in the consolidated balance sheet. ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018; early adoption is permitted. The provisions of ASU 2016-02 are to be applied using a modified retrospective approach. The Company is currently evaluating the impact of the adoption of this standard on its consolidated 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 July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842, Leases*. The amendments in this Update affect the amendments in Update 2016-02, which are not yet effective, but for which early adoption upon issuance is permitted. For entities that early adopted Topic 842, the amendments are effective upon issuance of this Update, and the transition requirements are the same as those in Topic 842. For entities that have not adopted Topic 842, the effective date and transition requirements will be the same as the effective date and transition requirements in Topic 842. The provisions of ASU 2018-10 are to be applied using a modified retrospective approach. The Company is currently evaluating the impact of the adoption of this standard on its 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 condensed consolidated financial statement presentation or disclosures. For a more detailed listing of the Company's significant accounting policies, see Note 1 – "Organization and Summary of Significant Accounting Policies," of the notes to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC on March 22, 2018.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**2. LOAN PAYABLE**

On February 5, 2013, the Company entered into the CIRM Loan Agreement, pursuant to which CIRM agreed to disburse approximately \$19.8 million to the Company over a period of approximately three and one-half years to support Phase II of our ALLSTAR clinical trial. Under the CIRM Loan Agreement, the Company was required to repay the CIRM loan with interest at maturity. So long as the Company was not in default, the Loan Agreement had provisions allowing for forgiveness of the debt after the end of the project period, if the Company elected to abandon the project under certain circumstances.

On November 17, 2017, the Company gave notice to CIRM that it was electing to abandon the CIRM-funded project pursuant to the Loan Agreement. On December 11, 2017, Capricor and CIRM entered into Amendment No. 3 to the CIRM Notice of Loan Award whereby the total loan balance consisting of principal and accrued interest under the CIRM Loan Agreement has been forgiven by CIRM thereby terminating Capricor and the Company's obligation to repay the loan balance. The Company has classified the forgiveness of the loan payable consisting of principal and accrued interest of approximately \$15.7 million as "other income" in our Consolidated Statement of Operations and Comprehensive Income (Loss) for the period ending December 31, 2017. The decision to terminate the Loan Award and forgive the loan balance was due to the abandonment of the ALLSTAR project at the end of the project period in accordance with Section 4.10 of the Loan Agreement and Article VII, Section I of the CIRM Loan Administration Policy.

For the three months ended September 30, 2018 and 2017, interest expense under the CIRM loan was zero and \$107,653, respectively. For the nine months ended September 30, 2018 and 2017, interest expense under the CIRM loan was zero and \$318,500, respectively.

**3. STOCKHOLDER'S EQUITY**

March 2017 Common Stock Sales Agreement

On March 31, 2017, the Company entered into a Sales Agreement with Wainwright, under which the Company from time to time, issued and sold shares of its common stock through Wainwright as sales agent in an at-the-market offering under a prospectus supplement for aggregate sales proceeds of \$5.0 million (the "March 2017 ATM Program"). The common stock was distributed at the market prices prevailing at the time of sale. The Company sold an aggregate of 2,589,078 common shares under the March 2017 ATM Program at an average price of approximately \$1.93 per

common share for gross proceeds of approximately \$5.0 million. The Company paid 3.0% cash commission on the gross proceeds, plus reimbursement of expenses of the placement agent and legal fees in the aggregate amount of approximately \$0.2 million. The March 2017 ATM Program became fully utilized in October 2017.

#### May 2017 Financing

On May 5, 2017, the Company entered into Subscription Agreements with certain accredited investors (the “Investors”), pursuant to which the Company agreed to issue and sell to the investors, in a private placement (the “Private Placement”), an aggregate of 1,196,291 shares of its common stock, par value \$0.001 per share, at a price per share of \$3.10 for an aggregate purchase price of approximately \$3.7 million. This placement included participation from some of the Company’s directors.

In connection with the Private Placement, the Company also entered into a Registration Rights Agreement with the Investors. Pursuant to the terms of the Registration Rights Agreement, the Company was obligated (i) to prepare and file with the SEC a registration statement to register for resale the shares issued in the Private Placement, and (ii) to use its reasonable best efforts to cause the registration statement to be declared effective by the SEC as soon as practicable, in each case subject to certain deadlines. The Company will be required to pay to each Investor liquidated damages equal to 1.0% of the aggregate purchase price paid by such Investor pursuant to the Subscription Agreements for the shares per month (up to a cap of 10.0%) if it does not meet certain obligations with respect to the registration of the shares, subject to certain conditions. Pursuant to its obligations under the Registration Rights Agreement, the Company registered for resale the shares issued in the Private Placement pursuant to a registration statement on Form S-3 (File No. 333-219188), which was filed with the SEC on July 7, 2017 and declared effective on July 17, 2017.

**CAPRICOR THERAPEUTICS, INC.****Notes to CONDENSED CONSOLIDATED financial statements****(unaudited)****3. STOCKHOLDER'S EQUITY (Continued)**October 2017 Common Stock Sales Agreement

On October 19, 2017, the Company entered into the October Sales Agreement with Wainwright, establishing the October 2017 ATM Program. The common stock sold in the October 2017 ATM Program will be distributed at the market prices prevailing at the time of sale. The October 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 plus reimbursement of certain expenses. Through the first three quarters of 2018, the Company sold an aggregate of 4,073,160 shares under the October 2017 ATM Program at an average price of approximately \$1.57 per common share for net proceeds of approximately \$6.2 million. From the inception of the October 2017 ATM Program through November 13, 2018, the Company sold an aggregate of 5,417,750 shares under the October 2017 ATM Program at an average price of approximately \$1.75 per common share for net proceeds of approximately \$9.2 million (see Note 10 – “Subsequent Events”). The Company paid 3.0% cash commission on the gross proceeds, plus reimbursement of expenses of the placement agent and legal fees in the aggregate amount of approximately \$0.3 million.

Outstanding Shares

At September 30, 2018, the Company had 30,748,872 shares of common stock issued and outstanding.

**4. STOCK AWARDS, WARRANTS AND OPTIONS**Warrants

The following table summarizes all warrant activity for the period ended September 30, 2018:

|                                | Warrants  | Weighted Average<br>Exercise Price |
|--------------------------------|-----------|------------------------------------|
| Outstanding at January 1, 2018 | 1,081,716 | \$ 4.01                            |

|                                   |           |         |
|-----------------------------------|-----------|---------|
| Granted                           | -         | -       |
| Exercised                         | -         | -       |
| Expired                           | -         | -       |
| Outstanding at September 30, 2018 | 1,081,716 | \$ 4.01 |

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

| Grant Date | Warrants Outstanding  |                   | Exercise Price<br>per Share | Expiration<br>Date |
|------------|-----------------------|-------------------|-----------------------------|--------------------|
|            | September<br>30, 2018 | December 31, 2017 |                             |                    |
| 11/20/2013 | 235,643               | 235,643           | \$ 2.27                     | 11/20/2018         |
| 3/16/2016  | 846,073               | 846,073           | \$ 4.50                     | 3/16/2019          |
|            | 1,081,716             | 1,081,716         |                             |                    |

#### Restricted Stock

In December 2017, the Company entered into an agreement with a consulting firm pursuant to which the Company agreed to grant 12,500 shares of restricted stock, which fully vested in February 2018 upon completion of services. In June 2018, the Company granted the consulting firm an additional 16,666 shares of restricted stock which was fully vested. The 29,166 shares of restricted stock issued by the Company was valued at \$46,250. The fair value of the restricted stock was determined using the Company's closing stock price on the vesting date. Furthermore, in June 2018, the Company agreed that at the end of December 2018, provided that the agreement has not been terminated earlier by either party, Capricor will issue 4,166 shares of restricted stock for each full month during which services were performed from and after June 2018.



**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

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

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, 4,149,710 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 4,149,710 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). Additionally, in connection with the proposed increase in the total number of shares of common stock that may be issued under the 2012 Plan, the Company increased the number of shares of common stock that may be issued pursuant to options that are intended to qualify as incentive stock options from 4,149,710 shares to 4,474,809 shares. The Third Amendment to the 2012 Plan provided that an additional 325,099 shares be added to the 2012 Plan for the fiscal year 2016. In addition, for the fiscal years beginning on January 1, 2018 and 2017, the amount of shares that were added was equal to 525,409 and 427,980 shares, respectively.

At the time the merger between Capricor and Nile became effective, 2,697,311 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, 2018 was approximately \$1.05. No options were granted during the three months ended September 30, 2017. The estimated weighted average fair value of the options granted during the nine months ended September 30, 2018 and 2017 were approximately \$1.31 and \$1.91 per share, respectively.

The Company estimates the fair value of each option award using the Black-Scholes option-pricing model. The Company used the following assumptions to estimate the fair value of stock options issued during the nine months ended September 30, 2018 and 2017:

|                          | <b>September 30, 2018</b> | <b>September 30, 2017</b> |
|--------------------------|---------------------------|---------------------------|
| Expected volatility      | 137% - 145%               | 78% - 135%                |
| Expected term            | 5 - 6 years               | 5 - 10 years              |
| Dividend yield           | 0%                        | 0%                        |
| Risk-free interest rates | 2.3 - 3.0%                | 2.0% - 2.3%               |

**CAPRICOR THERAPEUTICS, INC.****Notes to CONDENSED CONSOLIDATED financial statements****(unaudited)****4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)**

Employee and non-employee stock-based compensation expense for the three and nine months ended September 30, 2018 and 2017 was as follows:

|                            | Three months ended September 30, |            | Nine months ended September 30, |              |
|----------------------------|----------------------------------|------------|---------------------------------|--------------|
|                            | 2018                             | 2017       | 2018                            | 2017         |
| General and administrative | \$ 283,282                       | \$ 299,515 | \$ 878,598                      | \$ 899,307   |
| Research and development   | 147,151                          | 127,967    | 409,932                         | 398,055      |
| Total                      | \$ 430,433                       | \$ 427,482 | \$ 1,288,530                    | \$ 1,297,362 |

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. We account 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, 2018:

|                                | Number of<br>Options | Weighted Average<br>Exercise Price | Aggregate<br>Intrinsic Value |
|--------------------------------|----------------------|------------------------------------|------------------------------|
| Outstanding at January 1, 2018 | 6,873,903            | \$ 1.62                            | \$ -                         |
| Granted                        | 994,678              | 1.42                               |                              |
| Exercised                      | (376,055 )           | 0.37                               |                              |
| Expired/Cancelled              | (205,539 )           | 2.57                               |                              |

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|                                   |           |    |      |    |   |
|-----------------------------------|-----------|----|------|----|---|
| Outstanding at September 30, 2018 | 7,286,987 | \$ | 1.64 | \$ | - |
| Exercisable at September 30, 2018 | 5,907,417 | \$ | 1.51 | \$ | - |

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 \$521,678 for the nine months ended September 30, 2018.

## 5. 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, 2018, the Company maintained approximately \$10.5 million of uninsured deposits.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**6. 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 after the award period end date, estimated to be in 2019, 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 would be five years from the date of execution of the applicable loan agreement; provided that the term of the loan will not exceed ten years from the date on which the CIRM Award was granted. 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.

In 2016, Capricor received \$3.1 million under the terms of the CIRM Award. In September 2017, the Company 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, 2018, the Company's liability balance for the CIRM Award was \$3.4 million, of which approximately \$0.4 million is recorded as restricted cash, due to the fact that Capricor is required to expend approved project costs in order to use these funds.

On August 8, 2017, we entered into an Amendment to the CIRM Notice of Award pursuant to which CIRM approved the Company'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") which will 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, we 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.

#### 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 September 30, 2018, approximately \$0.7 million has been incurred under the terms of the NIH grant award. At this time, we are continuing to evaluate this program and have not yet made a determination as to whether we will continue into clinical development for this indication.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

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

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 two years, subject to annual and quarterly reporting requirements. As of September 30, 2018, approximately \$1.5 million has been incurred under the terms of the award.

**7. COMMITMENTS AND CONTINGENCIES**

Leases

Capricor leases space for its corporate offices 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. On May 25, 2016, Capricor entered into a Third Amendment to Lease (the "Third Lease Amendment") with The Bubble Real Estate Company, LLC. Under the terms of the Third Lease Amendment, the lease term extension commenced on July 1, 2016 and will end on December 31, 2018. The base rent increased to \$22,995 per month for the first twelve months of the term, commencing July 1, 2016, increased to \$23,915 per month for the second twelve months of the term, commencing July 1, 2017, and, thereafter, increased to \$24,872 per month for the remainder of the lease term, commencing July 1, 2018. The Company is currently in discussions with The Bubble Real Estate Company, LLC to extend the term of our current lease for an additional one-year period.

The Facilities Lease which Capricor entered into with CSMC is for a term of three years commencing June 1, 2014 and replaced the month-to-month lease that was previously in effect between CSMC and Capricor. The monthly lease payment under the Facilities Lease was \$15,461 per month for the first six months of the term and increased to \$19,350 per month for the remainder of the term. The amount of rent expense is subject to annual adjustments according to increases in the Consumer Price Index. The Facilities Lease expired on May 31, 2017 and transitioned to a month-to-month tenancy. On August 10, 2017, the Company and CSMC entered into the First Amendment to the Facilities Lease effective August 1, 2017 (the "First Amendment") pursuant to which the term of the Facilities Lease was extended for an additional 12-month period, and the Company was granted an option to further extend the term for an additional 12-month period thereafter through July 31, 2019. Under the First Amendment, the total monthly

rent increased from \$19,350 to \$19,756. In addition, pursuant to the First Amendment, the premises covered by the Facilities Lease now also include the manufacturing facility currently being utilized by Capricor. In lieu of further increasing the monthly rental payment set forth in the First Amendment, the Company has also agreed to provide doses of CAP-1002 for use in CSMC's clinical trials for a negotiated amount of monetary compensation. On July 19, 2018, the Company exercised its option to extend the term of the Facilities Lease with CSMC for an additional 12-month period through July 31, 2019. The monthly lease payment for the extended term will remain at \$19,756. On September 7, 2018, Capricor entered into a Second Amendment to the CSMC Facilities Lease pursuant to which Capricor was granted two consecutive 1-year options to extend the term of the Facilities Lease through July 31, 2021.

In addition, the Company entered into a month-to-month lease agreement with University Center Lane Tenant, LLC, pursuant to which the Company leases office space located in San Diego, California. The lease commenced March 1, 2018 and the rental payment is currently \$4,190 per month.

Included within the table below, future minimum rental payments to related parties totaled \$197,560. A summary of future minimum rental payments required under operating leases as of September 30, 2018 is as follows:

| Years ended     | Operating Leases |
|-----------------|------------------|
| 2018 (3 months) | \$ 133,884       |
| 2019            | 138,292          |

Expenses incurred under operating leases to unrelated parties was \$83,785 and \$71,215 for the three months ended September 30, 2018 and 2017, respectively, and \$244,835 and \$213,646 for the nine months ended September 30, 2018 and 2017, respectively. Expenses incurred under operating leases to related parties was \$59,268 and \$58,862 for the three months ended September 30, 2018 and 2017, respectively, and \$177,804 and \$171,721 for the nine months ended September 30, 2018 and 2017, respectively.



**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

(unaudited)

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

Legal Proceedings

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.

**8. 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.

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.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**8. LICENSE AGREEMENTS (Continued)**

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 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.

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.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**8. LICENSE AGREEMENTS (Continued)**

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.

*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.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**8. LICENSE AGREEMENTS (Continued)**

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.

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 for a period of 90 days after its receipt of written notice from CSMC of its intent to exercise its option.



**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**8. LICENSE AGREEMENTS (Continued)**

*Collaboration Agreement with Janssen Biotech, Inc.*

On December 27, 2013, Capricor entered into a Collaboration Agreement and Exclusive License Option (the “Janssen Agreement”) with Janssen, a wholly-owned subsidiary of Johnson & Johnson. Under the terms of the Janssen Agreement, Capricor and Janssen agreed to collaborate on the development of Capricor’s cell therapy program for cardiovascular applications, including its lead product candidate, CAP-1002. Capricor and Janssen further agreed to collaborate on the development of cell manufacturing in preparation for future clinical trials. Under the Janssen Agreement, Capricor was paid \$12.5 million, and Capricor agreed to contribute to the development of a chemistry, manufacturing and controls package. In addition, Janssen had the exclusive right to enter into an exclusive license agreement pursuant to which Janssen would have received a worldwide, exclusive license to exploit CAP-1002 as well as certain CSps and CDCs in the field of cardiology.

On June 30, 2017, Capricor was informed by Janssen that Janssen would not be exercising its exclusive option right to exploit CAP-1002 as well as certain CSps and CDCs in the field of cardiology. Capricor will retain full rights to CAP-1002 in all indications as a result of this decision. Capricor will also have an irrevocable, fully paid-up non-exclusive license under patents controlled by Janssen utilized in the production of the clinical trial materials manufactured pursuant to the CMC development plan between Capricor and Janssen and a non-exclusive perpetual license to publish, disclose and use the information of Janssen that was utilized in the production of the clinical trial materials manufactured pursuant to the CMC development plan. On August 7, 2018, the Company entered into an Exclusive License Agreement with Janssen pursuant to which Janssen granted Capricor an exclusive worldwide license to all rights to Janssen’s know-how to exploit CDC-cells and CDC-product in the field as described in the previous Janssen Agreement.

Company’s Technology - Cenderitide and CU-NP

The Company entered into an exclusive license agreement for intellectual property rights related to natriuretic peptides with the Mayo Foundation for Medical Education and Research (“Mayo”), a Clinical Trial Funding Agreement with Medtronic, Inc. (“Medtronic”), and a Transfer Agreement with Medtronic, all of which also include certain intellectual property licensing provisions. In February 2017, we elected to terminate our former natriuretic peptide development program, consisting of Cenderitide (CD-NP) and CU-NP, so as to more efficiently focus our resources and efforts on our CAP-1002 and CAP-2003 programs.

*Medtronic Clinical Trial Funding Agreement*

In February 2011, the Company entered into a Clinical Trial Funding Agreement with Medtronic, related to the Company's now discontinued Cenderitide program. Pursuant to its terms, the agreement expired in February 2012. Although the Medtronic agreement expired, there are certain provisions that survive the expiration of the agreement, including the obligation to pay royalties on products that might be covered by the agreement. The Company and Medtronic subsequently entered into a Transfer Agreement, described below.

*Medtronic Transfer Agreement*

On October 8, 2014, the Company entered into a Transfer Agreement (the "Transfer Agreement") with Medtronic to acquire patent rights relating to the Company's now discontinued natriuretic peptides program. Pursuant to the Transfer Agreement, Medtronic assigned to the Company all of its right, title and interest in all natriuretic peptide patents and patent applications previously owned by Medtronic or co-owned by Medtronic and the Company (the "Natriuretic Peptide Patents").

In light of the Company's decision to terminate its development program with respect to natriuretic peptides, the Company elected to cease prosecution of all of the Natriuretic Peptide Patents and has offered to reassign to Medtronic rights to certain patent applications obtained through the Transfer Agreement. Medtronic elected not to take a reassignment of the patent rights.

**CAPRICOR THERAPEUTICS, INC.**

**Notes to CONDENSED CONSOLIDATED financial statements**

**(unaudited)**

**9. RELATED PARTY TRANSACTIONS**

Lease and Sub-Lease Agreement

As noted above, Capricor is a party to lease agreements with CSMC, which holds more than 10% of the outstanding capital stock of Capricor Therapeutics (see Note 7 – “Commitments and Contingencies”), and CSMC has served as an investigative site in Capricor’s clinical trials. Additionally, Dr. Eduardo Marbán, who holds more than 10% 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 month periods ended September 30, 2018 and 2017, Capricor recognized \$7,500 in sublease income from the related party. For each of the nine month periods ended September 30, 2018 and 2017, 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

Effective January 1, 2013, Frank Litvack, the Company’s Executive Chairman and a member of its Board of Directors, entered into an oral Consulting Agreement with Capricor whereby Capricor agreed to pay Dr. Litvack fees of \$10,000 per month for consulting services. On March 24, 2014, Capricor entered into a written Consulting Agreement with Dr. Litvack memorializing the \$10,000 per month compensation arrangement described above. The agreement is terminable upon 30 days’ notice. Additionally, beginning in 2016, Capricor retained the services of Lit Digital Media, LLC whose sole member is Harry Litvack, the son of Frank Litvack. Lit Digital Media provides services to the Company related to social media and public relations, and the Company pays Lit Digital Media approximately \$1,500 per month for such services.

Payables to Related Party

At September 30, 2018 and December 31, 2017, the Company had accounts payable and accrued expenses to related parties totaling \$132,347 and \$174,424, respectively. CSMC accounts for \$130,837 and \$160,566 of the total accounts payable and accrued expenses to related parties as of September 30, 2018 and December 31, 2017, respectively. CSMC expenses relate to research and development and clinical trial costs. During the nine months ended September 30, 2018 and 2017, the Company paid CSMC approximately \$570,000 and \$1,002,000, respectively, for research and development, clinical trial expenses, rent and other expenses.

#### 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, 2018 and 2017, the Company recognized approximately \$47,000 and \$52,500, respectively, as other income. For the nine months ended September 30, 2018 and 2017, the Company recognized approximately \$257,000 and \$52,500, respectively, as other income. As of September 30, 2018 and December 31, 2017, approximately \$59,000 and \$122,500 was outstanding and recorded in prepaid expenses and other current assets, respectively.

#### 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. will provide clinical trial services to Capricor for its HOPE-2 clinical trial. The estimated costs to us are anticipated to be approximately \$250,000 for the duration of the project.

### **10. SUBSEQUENT EVENTS**

#### October 2017 Common Stock Sales Agreement

Subsequent to September 30, 2018 and through November 13, 2018, the Company sold an aggregate of 318,487 common shares under the October 2017 ATM Program at an average price of approximately \$1.07 per common share for net proceeds of approximately \$0.3 million. The Company paid 3.0% cash commission on the gross proceeds, plus reimbursement of expenses of the placement agent in the aggregate amount of approximately \$11,200.



## **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., 2<sup>nd</sup> Floor, Beverly Hills, California 90211. Our telephone number is (310) 358-3200 and our Internet address is [www.capricor.com](http://www.capricor.com).

### **Consummation of the Merger**

We were originally incorporated in Delaware in August 2005 under the name Nile Pharmaceuticals, Inc. and we changed our name to Nile Therapeutics, Inc., or Nile, in January 2007. On November 20, 2013, pursuant to that certain Agreement and Plan of Merger and Reorganization dated as of July 7, 2013, as amended by that certain First Amendment to Agreement and Plan of Merger and Reorganization dated as of September 27, 2013, or as amended, the Merger Agreement, by and among Nile, Nile’s wholly-owned subsidiary, Bovet Merger Corp., a Delaware corporation, or Merger Sub, and Capricor, Merger Sub merged with and into Capricor and Capricor became a wholly-owned subsidiary of Nile (referred to herein as the Merger). Immediately prior to the effective time of the merger, and in connection therewith, Nile filed certain amendments to its certificate of incorporation which, among other things (i) effected a 1-for-50 reverse split of its common stock, (ii) changed its corporate name from “Nile Therapeutics, Inc.” to “Capricor Therapeutics, Inc.,” and (iii) effected a reduction in the total number of authorized shares of common stock from 100,000,000 to 50,000,000, and a reduction in the total number of authorized shares of preferred stock from 10,000,000 to 5,000,000.

Capricor, our wholly-owned subsidiary, was founded in 2005 as a Delaware corporation based on the innovative work of its founder, Eduardo Marbán, M.D., Ph.D., and his collaborators. First located in Baltimore, Maryland, adjacent to The Johns Hopkins University, or JHU, where Dr. Marbán was chief of cardiology, Capricor moved to Los Angeles, California in 2007 when Dr. Marbán became Director of the Heart Institute at Cedars-Sinai Medical Center, or CSMC. Capricor's laboratories and manufacturing facilities are located in space that Capricor leases from CSMC.

### *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 are focused on CAP-1002 and CAP-2003. CAP-1002 is the subject of three clinical trials, in which the patients are in long-term follow-up. We are also now enrolling a new clinical trial of CAP-1002 in patients with DMD called HOPE-2 and have completed enrollment of an open label extension of the first HOPE-Duchenne trial.

CAP-1002 is also currently being investigated in two additional trials sponsored by 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 trials, we are providing the CAP-1002 investigational product for use in the trials.

We are evaluating CAP-2003 in pre-clinical studies for the treatment of various indications. CAP-1001 (autologous CDCs) was the subject of the CSMC and 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 seen in pre-clinical models 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, has been shown to increase exercise capacity and diaphragmatic function.

### **Phase II HOPE-2 Clinical Trial**

We are currently enrolling our HOPE-2 clinical trial. The clinical trial will 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 on a stable regimen of systemic glucocorticoids.

HOPE-2 is a randomized, double-blind, placebo-controlled clinical trial which will be conducted at approximately 10-15 sites located in the United States. It will enroll approximately 84 boys and young men with Duchenne muscular dystrophy. Participants will receive four doses of CAP-1002 or placebo – once every three months – over a one-year period.

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.

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 Biologics License Application, or BLA.

The primary efficacy endpoint will be 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 a validated test for skeletal muscle function in DMD called the Performance of the Upper Limb, or PUL, test. The PUL test is an outcomes instrument that was specifically designed to assess upper limb function in ambulant and non-ambulant patients with DMD. HOPE-2 will focus on the mid-level dimension of the PUL – or the ability to use muscles from the elbow to the fingers, which are essential for operating wheelchairs and performing other daily functions. HOPE-2 will measure the change from the beginning of the trial, or baseline, to Month 12. In HOPE-2, we also include additional secondary and exploratory endpoints which include cardiac function, pulmonary function testing, quality of life and additional measures. Enrollment commenced in April 2018. An interim analysis is planned to assess futility. The 12-month results are estimated to be available in the third quarter of 2020. The timing of both analyses will be dependent on enrollment rates and various other factors, including the availability of resources.

### **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 is being funded in part through a grant award from the California Institute for Regenerative Medicine, or CIRM.

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 22nd Annual International Congress of the World Muscle Society in October 2017. The patients are now in long-term follow-up.

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 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). Among the lower-functioning patients, defined as patients with a baseline mid-distal PUL score  $< 55$  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.

We have completed enrollment of our HOPE-Duchenne Open Label Extension clinical trial where 8 patients who were randomized into the control group of the HOPE-Duchenne trial have been given doses of CAP-1002.

### **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:**

#### **Phase I/II ALLSTAR Clinical Trial**

The Phase I portion of the ALLSTAR trial was a 14-patient, open-label, dose-escalation study that was conducted to evaluate the clinical safety of CAP-1002 in patients who had experienced a large heart attack and who had residual cardiac dysfunction. Each patient received a single infusion of CAP-1002 into the coronary artery most closely associated with the location of their MI, at a dose level of either 12.5 million or 25 million cells. The primary safety endpoints focused on the potential adverse effects of CAP-1002 delivery, including potential immunologic consequences of infusing cells that had originated from an unrelated donor. Event rates observed for each of the four pre-specified safety endpoints (acute myocarditis possibly attributable to CAP-1002; death due to ventricular tachycardia or ventricular fibrillation; sudden death; and major adverse cardiac events) were 0% over one and 12 months following CAP-1002 infusion.

This Phase I study was funded in large part by a grant received from the National Institutes of Health, or NIH.

Capricor began enrollment of the Phase II ALLSTAR study in the first quarter of 2014. This randomized, double-blind, placebo-controlled trial was designed to determine if treatment with CAP-1002 can reduce scar size in patients who have suffered an MI and other endpoints. At the time of randomization, patients were stratified into one of two cohorts according to the time since the occurrence of their MI (either 30 to 90 days after the MI, or greater than 90 days up to one-year after the MI). Following infusion, patients were to be followed for periodic evaluations over the course of one year. Patients were randomized in a 2:1 ratio to receive an infusion of CAP-1002 (25 million cells) or placebo, respectively, into the coronary artery most closely associated with the region of their MI. The trial was powered to detect a reduction in scar size, relative to placebo, as measured by MRI at the 12-month follow-up. In addition to evaluating CAP-1002 according to changes in scar size, ALLSTAR also evaluated CAP-1002 according to a variety of clinical and quality of life endpoints. The Phase II portion of the ALLSTAR trial was funded in large part

through the support of CIRM.

In October 2016, we announced completion of enrollment of the Phase II portion of the ALLSTAR trial in which 142 subjects were randomized to the active or control treatment groups in a 2:1 ratio, respectively, and of whom 134 received a single infusion of either CAP-1002 or placebo into the infarct-associated coronary artery. Patients in the trial were enrolled at approximately 30 centers in the United States and in Canada.

In May 2017, we announced that a pre-specified administrative interim analysis performed on six-month follow-up data from the ALLSTAR trial demonstrated a low probability (futility) of achieving a statistically-significant difference in the 12-month primary efficacy endpoint of percent change from baseline infarct size as a percentage of left ventricular mass, measured by cardiac MRI. At six months, a near-statistically-significant ( $p=0.05$ ) reduction of mean end-diastolic volume, as well as a trend of reduction of mean end-systolic volume, were seen in the CAP-1002 treatment group. There was no notable difference between treatment groups with respect to the change in ejection fraction. There were no safety signals in the CAP-1002 treatment cohort. Based on the results of the interim analysis, we elected to forego further MRI analyses and transition all patients in ALLSTAR to long-term follow-up.

### **Phase I/II DYNAMIC Clinical Trial**

The Phase I/II DYNAMIC trial, of which the Phase I portion has concluded, was designed to evaluate the safety and efficacy of CAP-1002 in the treatment of patients with advanced heart failure resulting from dilated cardiomyopathy of either ischemic or non-ischemic origin. This condition is characterized by chronic structural and functional abnormalities present throughout the heart's contractile tissue. In the DYNAMIC trial, CAP-1002 was infused into all three main coronary arteries to obtain broad exposure. Following infusion, patients were followed for one year. The trial was funded in part through a grant award from the NIH.

We initiated the open-label, dose-escalating Phase I portion of the DYNAMIC trial in December 2014 at a single center, CSMC, and in April 2015, completed enrollment with 14 patients with New York Heart Association, or NYHA, Class III heart failure. Each patient was administered CAP-1002 via a one-time, triple coronary infusion at one of several evenly-divided dose levels (37.5 million, 50 million, 62.5 million, or 75 million cells total). Initial top-line six-month results were presented at the American Heart Association's Annual Scientific Sessions in November 2015. Multi-vessel intracoronary infusion of CAP-1002 in subjects with dilated cardiomyopathy was shown to be safe in this study with no major adverse cardiac events reported at one month or at six months post-infusion. Although this trial was intended as a safety study, the six-month data demonstrated encouraging and congruent preliminary efficacy signals in multiple parameters, including ejection fraction, ventricular volumes, exercise capacity and subjective well-being.

In June 2016, Capricor reported positive 12-month data from the DYNAMIC study. For the 12 patients available for follow-up at one year, improvements from baseline in key cardiac function and dimensional indices that had been observed at six months were directionally maintained. Importantly, the change in median left ventricular ejection fraction from baseline to 12 months maintained its level of statistical significance that was shown at six months ( $p=0.02$  at both time points) and, on an absolute basis, continued to improve from six to 12 months. Of the five NYHA Class III subjects who received the highest dose of CAP-1002 (75 million cells), two subjects improved by two Classes (to Class I) and three improved by one Class (to Class II) at six months. At 12 months, three of these five subjects were assessed as Class I and two as Class II, demonstrating further improvement and indicating durability of the benefit of CAP-1002 on heart failure status for as long as one year following administration. CAP-1002 infusion was well-tolerated in DYNAMIC. Two of the 14 patients, who were in the lower two of the four dose cohorts, died from progressive heart failure approximately one and three months prior to study conclusion. Although we have designed a Phase II study to evaluate CAP-1002 in the heart failure population, at this time, we have no plans to conduct the Phase II portion of the DYNAMIC trial.

### **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 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.

**CAP-2003:**

Extracellular vesicles ("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 cardiac, inflammatory and other conditions to explore the possible therapeutic benefits that CAP-2003 may possess. We are evaluating CAP-2003 in pre-clinical studies investigating their use in various indications, such as Graft-versus-host disease ("GVHD") and hypoplastic left heart syndrome ("HLHS"). It is unknown at this time when an IND will be submitted for any particular indication. Additionally, in pre-clinical studies, we are exploring CAP-2003 as a potential vehicle for delivering therapies to targeted tissues in the human body.

In July 2018, Capricor, Inc. 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. While we consider CSps an important asset, at present there is no plan to develop CSps as a therapeutic agent.

**Natriuretic Peptides:**

In February 2017, we elected to terminate our former natriuretic peptide development program, consisting of Cenderitide (CD-NP) and CU-NP, so as to more efficiently focus our resources and efforts on our CAP-1002 and CAP-2003 programs.

**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 NIH and the Department of Defense, or DoD, a payment from Janssen and a loan and grant award from CIRM.

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 condensed 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

*General and Administrative Expenses.* G&A expenses for the three months ended September 30, 2018 and 2017 were approximately \$1.3 million and \$1.1 million, respectively. The increase during the third quarter of 2018 of approximately \$0.2 million compared to the same period of 2017 is primarily attributable to an increase of approximately \$0.1 million related to increased headcount and salaries/recruiting and an increase of \$0.1 related to investor and public relations expenses.

G&A expenses for the nine months ended September 30, 2018 and 2017 were approximately \$3.8 million and \$3.5 million respectively. The increase during the first nine months of 2018 of approximately \$0.3 million compared to the same period of 2017 is primarily attributable to an increase of approximately \$0.1 million relates to increased headcount and salaries/recruiting, \$0.1 million related to general operating expenses, and an increase of \$0.1 million related to investor and public relations expenses.

*Research and Development Expenses.* R&D expenses for the three months ended September 30, 2018 and 2017 were approximately \$3.1 million and \$1.9 million, respectively. The increase of approximately \$1.2 million in the third quarter of 2018 compared to the same period of 2017 is primarily due to the clinical development activities of CAP-1002 (HOPE-Duchenne and HOPE-2 clinical trials). These activities resulted in an increase of approximately \$1.0 million. Furthermore, for the three months ended September 30, 2018, there was an increase of approximately \$0.2 million in research and development expenses primarily related to CAP-1002 and CAP-2003.

R&D expenses for the nine months ended September 30, 2018 and 2017 were approximately \$9.2 million and \$8.2 million, respectively. The increase of approximately \$1.0 million in the first nine months of 2018 over the same period of 2017 is primarily due to the clinical development activities of CAP-1002 (HOPE-Duchenne and HOPE-2 clinical trials). These activities resulted in an increase of approximately \$2.8 million. Furthermore, for the nine months ended September 30, 2018, there was a decrease of approximately \$1.3 million related to reduced clinical development expenses in connection with the ALLSTAR clinical trial. Additionally, there was a decrease of approximately \$0.6 million in research and development expenses primarily related to CAP-1002 for the nine months ended September 30, 2018 as compared to the same period in 2017.

### *Products Under Active Development*

*CAP-1002* – The development of CAP-1002 is in its developmental stages. We expect to spend approximately \$8.0 million to \$10.0 million during 2018 on the clinical development and manufacturing of CAP-1002, which expenses are primarily related to our HOPE-2 clinical trial, and manufacturing of CAP-1002. We have transitioned the

ALLSTAR study to long-term follow-up. We have entered into a Master Services Agreement with WuXi AppTech, Inc., or WuXi, for the development, manufacturing and testing of our CAP-1002 product candidate. WuXi owns and operates a cGMP compliant manufacturing facility with space and resources necessary to manufacture products. The Agreement allows us to begin our technology transfer process in anticipation of potential commercial scale manufacturing and/or later stage clinical trials. Concurrently, we are internally developing additional process development improvements in anticipation of commercial scale and/or later stage clinical trials which may affect the timing of our technology transfer. Our strategy for further development and technology transfer of CAP-1002 will depend to a large degree on the outcome of our HOPE-2 trial.

*CAP-2003* – We expect to spend approximately \$2.0 million to \$4.0 million during 2018 on pre-clinical and other research expenses related to the CAP-2003 program, a portion of which will be offset by our grant awards from the NIH and DoD. Capricor is currently engaged in pre-clinical testing of CAP-2003 to explore its therapeutic potential, including studies that would potentially enable an IND. We have received a grant for up to approximately \$4.2 million from the NIH to study CAP-2003 for HLHS as well as 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, 2018, the Company has up to approximately \$4.4 million available under these grants and awards for disbursement, pursuant to the terms of each of the respective awards.

*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. Seventeen patients received CAP-1001 and eight 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 eight patients in the control group had no significant change in scar size. At present, there is no plan for a 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.

*Cenderitide* – We acquired the rights to Cenderitide in 2006. In February 2017, we terminated the Amended and Restated Technology License Agreement with the Mayo Foundation for Medical Education and Research to more efficiently focus our resources and efforts on our CAP-1002 and CAP-2003 programs. We do not anticipate having any further material expenses with respect to this product candidate.

Our expenditures on current and future clinical development programs, particularly our CAP-1002 and CAP-2003 programs, are expected to be substantial and to increase in relation to our available capital resources. However, these planned expenditures are subject to many uncertainties, including the results of clinical trials and whether we develop any of our product candidates independently or with a partner. As a result, 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.

*Collaboration Income.* On June 30, 2017, Capricor was informed by Janssen that Janssen would not be exercising its exclusive license option under the Janssen Agreement. As a result, the Company did not recognize any collaboration

income during the three months ended September 30, 2018 and 2017.

Collaboration income for the nine months ended September 30, 2018 and 2017 was zero and approximately \$1.4 million.

*Grant Income.* Grant income for the three months ended September 30, 2018 and 2017 was approximately \$0.2 million and \$0.3 million, respectively. The decrease of approximately \$0.1 million was related to the pre-clinical phase of the NIH grant award coming to completion during the third quarter of 2018.

Grant income for each of the nine months ended September 30, 2018 and 2017 was approximately \$0.8 million.

*Other Income.* Other income for the three months ended September 30, 2018 and 2017 was approximately \$46,700 and \$52,500, respectively. Other income was related to providing cells for investigational purposes for clinical trials sponsored by CSMC, which began in the third quarter of 2017.

Other income for the nine months ended September 30, 2018 and 2017 was approximately \$0.3 million and \$0.1 million, respectively.

*Interest Expense.* Interest expense for the three months ended September 30, 2018 and 2017 was zero and \$107,653, respectively. The decrease in interest expense in the third quarter of 2018 as compared to the second quarter of 2017 is due to the forgiveness of the CIRM Loan Award in December 2017.

Interest expense for the nine months ended September 30, 2018 and 2017 was zero and \$318,500, respectively.

## Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of September 30, 2018 and December 31, 2017 and our net increase (decrease) in cash and cash equivalents for the nine months ended September 30, 2018 and 2017, 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, 2018              | December 31, 2017 |
| Cash and cash equivalents                            | \$ 4,378                        | \$ 6,140          |
| Working capital                                      | \$ 9,517                        | \$ 14,042         |
| Stockholders' equity                                 | \$ 6,980                        | \$ 11,227         |
|  |                                 |                   |
| Cash flow data                                       | Nine months ended September 30, |                   |
|  | 2018                            | 2017              |
| Cash provided by (used in):                          |                                 |                   |
| Operating activities                                 | \$ (10,091 )                    | \$ (11,564 )      |
| Investing activities                                 | 1,667                           | 7,966             |
| Financing activities                                 | 6,341                           | 8,554             |
| Net increase (decrease) in cash and cash equivalents | \$ (2,083 )                     | \$ 4,956          |

Our total cash and cash equivalents, not including restricted cash, as of September 30, 2018 was approximately \$4.4 million compared to approximately \$6.1 million as of December 31, 2017. The decrease in cash and cash equivalents from December 31, 2017 as compared to September 30, 2018 is due to general operating expenses. We incurred a net loss of approximately \$4.1 million for the three months ended September 30, 2018 compared to a net loss of approximately \$2.7 million in the same period of 2017, and we incurred a net loss of approximately \$11.9 million for the nine months ended September 30, 2018 compared to a net loss of approximately \$9.9 million in the same period of 2017. Additionally, we received approximately \$6.2 million of net proceeds as a result of our October 2017 ATM Program along with an allocation of marketable securities to cash and cash equivalents. Total marketable securities, consisting primarily of U.S. treasuries, were approximately \$6.0 million as of September 30, 2018, as compared to approximately \$8.0 million as of December 31, 2017. As of September 30, 2018, we had approximately \$5.3 million in total liabilities. As of September 30, 2018, we had approximately \$9.5 million in net working capital.

Cash used in operating activities was approximately \$10.1 million and \$11.6 million for the nine months ended September 30, 2018 and 2017, respectively. The difference of approximately \$1.5 million in cash from operating activities is primarily due to a change in accounts payable and accrued liabilities of approximately \$2.4 million and an increase of approximately \$1.4 million in the change in deferred revenue for the nine months ended September 30, 2018 as compared to the same period in 2017. Furthermore, there was a change of approximately \$0.3 million in accrued interest from the nine months ended September 30, 2018 as compared to the same period in 2017. These are offset by the increase in net loss of approximately \$2.1 million for the nine months ended September 30, 2018 as

compared to the same period of 2017. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, including as 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 \$1.7 million and \$8.0 million for the nine months ended September 30, 2018 and 2017, respectively. The decrease in cash provided by investing activities for the nine months ended September 30, 2018 as compared to the same period of 2017 is primarily due to the net effect from purchases, sales, and maturities of marketable securities. Additionally, there was an increase of approximately \$0.3 million in purchases of property and equipment during the nine months ended September 30, 2018 as compared to the same period of 2017.

We had cash flow provided by financing activities of approximately \$6.3 million and \$8.6 million for the nine months ended September 30, 2018 and 2017, respectively. The decrease in cash provided by financing activities for the nine months ended September 30, 2018 as compared to the same period of 2017 is primarily due to the net proceeds from the sale of common stock.

From inception through September 30, 2018, we financed our operations primarily through private and public sales of our equity securities, NIH and DoD grants, a payment from Janssen, a CIRM loan and a CIRM grant award. 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 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 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;
- 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***

***October 2017 Common Stock Sales Agreement.*** On October 19, 2017, the Company entered into a Common Stock Sales Agreement, or the October Sales Agreement, with Wainwright under which we may, 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 will be distributed at the market prices prevailing at the time of sale. The October 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. Any shares issued pursuant to the October 2017 ATM Program will be 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 (the “2015 S-3”). A prospectus supplement relating to the October 2017 ATM Program was filed with the SEC on October 19, 2017. On October 24, 2018, we filed a shelf registration statement on Form S-3 (File No. 333-227955) (the “2018 S-3”) with the SEC pursuant to Rule 415(a)(6) under the Securities Act of 1933, as amended. Accordingly, we may continue to issue and sell certain securities under the 2015 S-3, including pursuant to the October 2017 ATM Program, until the earlier of (i) the effective date of the 2018 S-3 and (ii) one hundred eighty days after the third anniversary of the initial effective date of the 2015 S-3.

As of November 13, 2018, the Company has sold an aggregate of 5,417,750 common shares under the October 2017 ATM Program at an average price of approximately \$1.75 per common share for net proceeds of approximately \$9.2 million.

**May 2017 Financing.** On May 5, 2017, the Company entered into subscription agreements with certain accredited investors, or the 2017 Investors, pursuant to which the Company agreed to issue and sell to the investors, in a private placement, or the 2017 Private Placement, an aggregate of 1,196,291 shares of its common stock, par value \$0.001 per share, at a price per share of \$3.10 for an aggregate purchase price of approximately \$3.7 million.

In connection with the 2017 Private Placement, the Company also entered into a Registration Rights Agreement with the 2017 Investors. Pursuant to the terms of the Registration Rights Agreement, the Company was obligated (i) to prepare and file with the SEC a registration statement to register for resale the shares issued in the 2017 Private Placement, and (ii) to use its reasonable best efforts to cause the registration statement to be declared effective by the SEC as soon as practicable, in each case subject to certain deadlines. The Company will be required to pay to each 2017 Investor liquidated damages equal to 1.0% of the aggregate purchase price paid by such 2017 Investor pursuant to the Subscription Agreements for the shares per month (up to a cap of 10.0%) if it does not meet certain obligations with respect to the registration of the shares, subject to certain conditions. Pursuant to its obligations under the Registration Rights Agreement, the Company registered for resale the shares issued in the 2017 Private Placement pursuant to a registration statement on Form S-3 (File No. 333-219188), which was filed with the SEC on July 7, 2017 and declared effective on July 17, 2017. The 2017 Private Placement included participation from certain of the Company's directors.

***March 2017 Common Stock Sales Agreement.*** On March 31, 2017, the Company entered into a Common Stock Sales Agreement, or the March Sales Agreement, with Wainwright under which we 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 \$5.0 million, or the March 2017 ATM Program. The common stock was distributed at the market prices prevailing at the time of sale. The March 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 March 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. A prospectus supplement relating to the March 2017 ATM Program was filed with the SEC on April 3, 2017.

The Company sold an aggregate of 2,589,078 common shares under the March 2017 ATM Program at an average price of approximately \$1.93 per common share for gross proceeds of approximately \$5.0 million. The March 2017 ATM Program became fully utilized in October 2017.

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

#### ***CIRM Loan Agreement***

Pursuant to the terms of the CIRM Loan Agreement, CIRM agreed to disburse \$19,782,136 to Capricor over a period of approximately three and one-half years to support Phase II of Capricor's ALLSTAR clinical trial. Under this award, we received approximately \$14.4 million in principal. So long as we were not in default, the Loan Agreement had provisions allowing for forgiveness of the debt after the end of the project period, if we elected to abandon the project under certain circumstances.

On November 17, 2017, we gave notice to CIRM that we were electing to abandon the CIRM-funded project pursuant to the Loan Agreement. On December 11, 2017, Capricor and CIRM entered into Amendment No. 3 to the CIRM Notice of Loan Award whereby the total loan balance under the CIRM Loan Agreement was forgiven by CIRM thereby terminating Capricor and the Company's obligation to repay the loan balance. The Company classified the forgiveness of the loan payable, consisting of principal and accrued interest, of approximately \$15.7 million as "other income" in our Consolidated Statement of Operations and Comprehensive Income (Loss) for the period ending December 31, 2017. The decision to terminate the Loan Award and forgive the loan balance was due to the abandonment of the ALLSTAR project at the end of the project period in accordance with Section 4.10 of the Loan Agreement and Article VII, Section I of the CIRM Loan Administration Policy.

### *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 after the award period end date, estimated to be in 2019, 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 would be five years from the date of execution of the applicable loan agreement; provided that the term of the loan will not exceed ten years from the date on which the CIRM Award was granted. 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.

In 2016, Capricor received \$3.1 million under the terms of the CIRM Award. In September 2017, the Company 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, 2018, the Company's liability balance for the CIRM Award was \$3.4 million, of which approximately \$0.4 million is recorded as restricted cash, due to the fact that Capricor is required to expend approved project costs in order to use these funds.

On August 8, 2017, we entered into an Amendment to the CIRM Notice of Award pursuant to which CIRM approved the Company'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, or CMO, which will 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, we 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.

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

In September 2016, Capricor was approved for a grant from the NIH to study CAP-2003 for 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 September 30, 2018, approximately \$0.7 million has been incurred under the terms of the NIH grant award. At this time, we are still in pre-clinical evaluation of this program and have not yet made a determination as to whether we will continue into clinical development for this indication.

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

In September 2016, Capricor was approved for a grant award from the DoD 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 two years, subject to annual and quarterly reporting requirements. As of September 30, 2018, approximately \$1.5 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, 2018.

### **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 superseded standards. 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.

#### ***Other 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. Other income is due upon billing. Other income is based on contracts with fixed transaction prices.

#### *Income from Collaborative Agreement*

Revenue from nonrefundable, up-front license or technology access payments under license and collaborative arrangements that are not dependent on any future performance by us is recognized when such amounts are earned. If we have continuing obligations to perform under the arrangement, such fees are recognized over the estimated period of the continuing performance obligation.

During 2017, the Company accounted for multiple element arrangements, such as license and development agreements in which a customer may purchase several deliverables, in accordance with FASB ASC Subtopic 605-25, *Multiple Element Arrangements*. For new or materially amended multiple element arrangements, the Company identified the deliverables at the inception of the arrangement and each deliverable within a multiple deliverable revenue arrangement was accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in the Company's control. The Company allocated revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, the Company determined the selling price for each deliverable using vendor-specific objective evidence, or VSOE, of selling price, if it exists, or third-party evidence, or TPE, of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, then the Company uses the best estimated selling price for that deliverable. Revenue allocated to each element was then recognized based on when the basic four revenue recognition criteria were met for each element.

We determined the deliverables under the Janssen Agreement did not meet the criteria to be considered separate accounting units for the purposes of revenue recognition. As a result, we recognized revenue from non-refundable, upfront fees ratably over the term of our performance under the agreement. The upfront payments received, pending recognition as revenue, were recorded as deferred revenue and were classified as a short-term or long-term liability on the condensed consolidated balance sheets and amortized over the estimated period of performance. We periodically reviewed the estimated performance period of our contract based on the progress of our project. As of June 30, 2017, the full amount of income had been recognized under the Janssen Agreement.

### ***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.

### ***Long-Term Debt***

Capricor historically accounted for the loan proceeds under its CIRM Loan Agreement as long-term liabilities. On November 17, 2017, we gave notice to CIRM that we were electing to abandon the CIRM-funded project pursuant to the Loan Agreement and on December 11, 2017, Capricor and CIRM entered into Amendment No. 3 to the CIRM Notice of Loan Award whereby the total loan balance under the CIRM Loan Agreement was forgiven by CIRM thereby terminating Capricor and the Company's obligation to repay the loan balance. The Company has classified the forgiveness of the loan payable consisting of principal and accrued interest of approximately \$15.7 million as "other income" in our Consolidated Statement of Operations and Comprehensive Income (Loss) for the period ending December 31, 2017.

### ***Restricted Cash***

We had two awards with CIRM designated for specific use, the CIRM Loan Agreement in connection with the ALLSTAR Phase II clinical trial and the CIRM Award related to the HOPE Phase I/II clinical trial. Restricted cash represents funds received under these awards which are to be allocated to the research costs as incurred. Generally, a reduction of restricted cash occurs when we deem certain costs are attributable to the respective award.

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

In May 2014, the FASB issued Accounting Standards Update (“ASU”) 2014-09, *Revenue from Contracts with Customers (Topic 606)* (“ASU 2014-09”). ASU 2014-09 amended the existing accounting standards for revenue recognition. ASU 2014-09 establishes principles for recognizing revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The Company adopted ASU 2014-09 and all subsequent updates related to this topic in the first quarter of 2018 using the modified retrospective approach. The adoption of this ASU was applied to only those contracts that were not completed upon the initial application. The adoption of this update did not have a material impact on the Company’s financial statements.

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 generally requires all leases to be recognized in the consolidated balance sheet. ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018; early adoption is permitted. The provisions of ASU 2016-02 are to be applied using a modified retrospective approach. The Company is currently evaluating the impact of the adoption of this standard on its consolidated 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 July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842, Leases*. The amendments in this Update affect the amendments in Update 2016-02, which are not yet effective, but for which early adoption upon issuance is permitted. For entities that early adopted Topic 842, the amendments are effective upon issuance of this Update, and the transition requirements are the same as those in Topic 842. For entities that have not adopted Topic 842, the effective date and transition requirements will be the same as the effective date and transition requirements in Topic 842. The provisions of ASU 2018-10 are to be applied using a modified retrospective approach. The Company is currently evaluating the impact of the adoption of this standard on its 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 condensed consolidated financial statement presentation or disclosures. For a more detailed listing of the Company's significant accounting policies, see Note 1 – "Organization and Summary of Significant Accounting Policies," of the notes to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC on March 22, 2018.

### **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, 2018, the fair value of our cash, cash equivalents, including restricted cash, and marketable securities was approximately \$10.8 million. Additionally, as of September 30, 2018, Capricor's portfolio was classified as cash, cash equivalents and marketable securities, which consisted primarily of money market funds and bank money market, which included short term U.S. treasuries, bank savings and checking accounts. Capricor did not have any investments with significant exposure to the subprime mortgage market issues.

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, 2018 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, 2017, as filed with the Securities and Exchange Commission on March 22, 2018, 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 the Company from time to time. Except as set forth below, there have been no material changes in our risk factors since the filing of our Annual Report on Form 10-K for the year ended December 31, 2017. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business.

#### **Risks Related to Our Business**

*If our business plans are not successful, we may not be able to continue operations as a going concern and our stockholders may lose their entire investment in us.*

There is substantial doubt about our ability to continue as a going concern. We have historically incurred substantial losses to fund our business operations including our research and development activities. We will, in all likelihood, sustain operating expenses without corresponding revenues for the foreseeable future. This may result in our incurring net operating losses that will increase continuously until we are able to obtain regulatory approval for, and commercialize, our product candidates, the occurrence of which cannot be assured. While we have historically been able to adjust the timing associated with our R&D efforts, as well as reducing headcount and implementing certain budget restrictions, to alleviate uncertainties surrounding our ability to continue as a going concern, if ultimately we cannot continue as a going concern, our stockholders may lose their entire investment in us.

#### **Risks Related to Our Common Stock**

*If our minimum bid price stays below \$1.00 per share for an extended period of time, our common stock may be subject to delisting from the Nasdaq Capital Market.*

Since November 9, 2018, the share price of our common stock has been below \$1.00, which is a requirement to remain listed on the Nasdaq Capital Market. If the share price of our common stock remains below \$1.00 or we fail to satisfy other listing requirements of the Nasdaq Capital Market, we may receive a notice of listing deficiency. To the extent that we receive a notice of a listing deficiency and are unable to resolve the share price or any other listing deficiency, there is a risk that our common stock may be delisted from Nasdaq and would likely trade only on the over-the-counter market (the “OTC”). We received notices of listing deficiencies on June 27, 2017 and June 29, 2017, and were able to resolve the deficiencies, but there is no assurance that we would be able to resolve any listing deficiency resulting in a notice of listing deficiency in the future. 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.

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**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 Commission 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 Commission 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 Commission 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 Commission 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 Commission on November 26, 2013).

3.3 Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the Commission on February 9, 2007).

4.1 Form of Warrant issued to Investors in March 2012 Registered Offering (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on April 2, 2012).

4.2 Form of Warrant, issued by the Company to the Investors on March 16, 2016 (incorporated by reference to Exhibit 4.2 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on March 16, 2016).

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, 2018 formatted in eXtensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017, (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2018 and September 30, 2017, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity for the period from December 31, 2017 through September 30, 2018, (iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and September 30, 2017, and (v) Notes to Condensed Consolidated

Financial Statements.\*

\* Filed herewith.

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**SIGNATURES**

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

**CAPRICOR THERAPEUTICS, INC.**

Date: November 14, 2018 By: /s/ Linda Marbán, Ph.D.  
Linda Marbán, Ph.D.  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 14, 2018 By: /s/ Anthony J. Bergmann  
Anthony J. Bergmann  
Chief Financial Officer  
(Principal Financial and Accounting Officer)