

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

**CEL SCI CORP**

**Form: 10-Q/A**

**Date Filed: 2020-08-11**

Corporate Issuer CIK: 725363

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-Q/A  
(Amendment No.1)**

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF  
THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended **June 30, 2020**  
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 **001-11889**

**CEL-SCI CORPORATION**

**Colorado**

State or other jurisdiction incorporation

**84-0916344**

(IRS) Employer Identification Number

**8229 Boone Boulevard, Suite 802  
Vienna, Virginia 22182**

Address of principal executive offices

**(703) 506-9460**

Registrant's telephone number, including area code

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

| Title of Each Class | Trading Symbol(s) | Name of Each Exchange on Which<br>Registered |
|---------------------|-------------------|--|
| Common Stock        | CVM               | NYSE American                                |

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) had been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check One):

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

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

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

| Class of Stock | No. Shares Outstanding | Date           |
|----------------|------------------------|----------------|
| Common         | 38,624,084             | August 5, 2020 |

## Explanatory Note

The purpose of this First Amendment to CEL SCI Corporation's Quarterly Report on Form 10-Q for the nine months ending June 30, 2020 (the "Form 10-Q"), as filed with the Securities and Exchange Commission on August 10, 2020 is to furnish Exhibits 101 to the Form 10-Q in accordance with Rule 201(c) and Rule 405 of Regulation S-T. Exhibits 101 provide the financial statements and related notes from the Form 10-Q formatted in XBRL (eXtensible Business Reporting Language).

No other changes have been made to the Form 10-Q. This First Amendment to the Form 10-Q continues to speak as of the original filing date of the Form 10-Q, does not reflect events that may have occurred subsequent to the original filing date, and does not modify or update in any way the disclosures made in the original Form 10-Q.

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CEL-SCI CORPORATION  
CONDENSED BALANCE SHEETS  
(UNAUDITED)

|  | <u>JUNE 30,</u><br><u>2020</u> | <u>SEPTEMBER 30,</u><br><u>2019</u> |
|--|--------------------------------|-------------------------------------|
| <b>ASSETS</b>  |                                |                                     |
| Current Assets:  |                                |                                     |
| Cash and cash equivalents  | \$ 20,136,789                  | \$ 8,444,774                        |
| Receivables  | 255,007                        | 62,765                              |
| Prepaid expenses   | 1,505,878                      | 524,953                             |
| Supplies used for R&D and manufacturing  | 787,011                        | 782,363                             |
| Total current assets   | 22,684,685                     | 9,814,855                           |
| Finance lease right of use assets  | 12,367,947                     | -                                   |
| Operating lease right of use assets  | 1,237,339                      | -                                   |
| Property and equipment, net  | 3,762,633                      | 15,825,636                          |
| Patent costs, net  | 311,346                        | 311,586                             |
| Deposits   | 1,670,917                      | 1,670,917                           |
| Total Assets   | <u>\$ 42,034,867</u>           | <u>\$ 27,622,994</u>                |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                                |                                     |
| Current Liabilities:   |                                |                                     |
| Accounts payable   | \$ 943,821                     | \$ 1,586,478                        |
| Accrued expenses   | 232,252                        | 34,432                              |
| Due to employees   | 543,132                        | 709,442                             |
| Derivative instruments, current portion  | 1,924,160                      | 674,442                             |
| Lease liabilities, current portion   | 1,007,868                      | -                                   |
| Other current liabilities  | -                              | 14,956                              |
| Total current liabilities  | 4,651,233                      | 3,019,750                           |
| Derivative instruments, net of current portion   | 5,094,172                      | 5,813,868                           |
| Finance lease obligations, net of current portion  | 11,995,197                     | 13,508,156                          |
| Operating lease obligations, net of current portion  | 1,154,325                      | -                                   |
| Other liabilities  | 125,000                        | 147,553                             |
| Total liabilities  | 23,019,927                     | 22,489,327                          |
| Commitments and Contingencies  |                                |                                     |
| <b>STOCKHOLDERS' EQUITY</b>  |                                |                                     |
| Preferred stock, \$.01 par value-200,000 shares authorized;<br>-0- shares issued and outstanding   | -                              | -                                   |
| Common stock, \$.01 par value - 600,000,000 shares authorized;<br>38,522,236 and 35,231,776 shares issued and outstanding<br>at June 30, 2020 and September 30, 2019, respectively | 385,223                        | 352,318                             |
| Additional paid-in capital   | 396,959,284                    | 358,507,603                         |

|   |                             |                             |
|---|-----------------------------|-----------------------------|
| Accumulated deficit                               | <u>(378,329,567)</u>        | <u>(353,726,254)</u>        |
| Total stockholders' equity                        | <u>19,014,940</u>           | <u>5,133,667</u>            |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b> | <b><u>\$ 42,034,867</u></b> | <b><u>\$ 27,622,994</u></b> |

See notes to condensed financial statements.

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CEL-SCI CORPORATION  
CONDENSED STATEMENTS OF OPERATIONS  
NINE MONTHS ENDED JUNE 30, 2020 and 2019  
(UNAUDITED)

|              | <u>2020</u> | <u>2019</u> |
|--------------|-------------|-------------|
| Grant income | \$ 530,106  | \$ 386,121  |

|  |                        |                        |
|--|------------------------|------------------------|
| Operating Expenses:  |                        |                        |
| Research and development                                       | 12,511,830             | 9,269,772              |
| General and administrative                                     | 8,389,821              | 5,667,510              |
| Total operating expenses                                       | <u>20,901,651</u>      | <u>14,937,282</u>      |
| Operating loss   | (20,371,545)           | (14,551,161)           |
| Other income   | 38,741                 | 54,575                 |
| Loss on derivative instruments                                 | (3,565,347)            | (3,316,384)            |
| Warrant inducement expense                                     | (805,753)              | -                      |
| Other non-operating gains                                      | 774,245                | 1,877,197              |
| Interest expense, net  | <u>(777,898)</u>       | <u>(1,350,774)</u>     |
| Net loss   | (24,707,557)           | (17,286,547)           |
| Modification of warrants                                       | <u>(21,734)</u>        | <u>-</u>               |
| Net loss available to common shareholders                      | \$ <u>(24,729,291)</u> | \$ <u>(17,286,547)</u> |
| Net loss per common share - basic and diluted                  | \$ (0.68)              | \$ (0.58)              |
| Weighted average common shares outstanding - basic and diluted | 36,230,092             | 30,046,241             |

See notes to condensed financial statements.

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CEL-SCI CORPORATION  
CONDENSED STATEMENTS OF OPERATIONS  
THREE MONTHS ENDED JUNE 30, 2020 and 2019  
(UNAUDITED)

|   | <u>2020</u>            | <u>2019</u>            |
|---|------------------------|------------------------|
| Grant income                                  | \$ 195,874             | \$ 108,938             |
| Operating Expenses:                           |                        |                        |
| Research and development                      | 3,912,870              | 2,965,512              |
| General and administrative                    | 3,192,403              | 2,353,525              |
| Total operating expenses                      | <u>7,105,273</u>       | <u>5,319,037</u>       |
| Operating loss                                | (6,909,399)            | (5,210,099)            |
| Other income                                  | 1,845                  | 18,448                 |
| Loss on derivative instruments                | (1,282,829)            | (7,905,519)            |
| Warrant inducement expense                    | (805,753)              | -                      |
| Other non-operating (losses) gains            | (950,935)              | 1,455,844              |
| Interest expense, net                         | <u>(273,708)</u>       | <u>(443,442)</u>       |
| Net loss available to common shareholders     | <u>\$ (10,220,779)</u> | <u>\$ (12,084,768)</u> |
| Net loss per common share - basic and diluted | \$ (0.27)              | \$ (0.37)              |



Weighted average common shares outstanding - basic and diluted

37,453,539

33,051,888

See notes to condensed financial statements.

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CEL-SCI CORPORATION  
STATEMENTS OF STOCKHOLDERS' EQUITY  
(UNAUDITED)

**Additional**

|   | Shares            | Amount            | Capital               | Deficit                 | Total                |
|---|-------------------|-------------------|-----------------------|-------------------------|----------------------|
| BALANCES AT OCTOBER 1, 2019                             | 35,231,776        | \$ 352,318        | \$ 358,507,603        | \$ (353,726,254)        | \$ 5,133,667         |
| Adoption of new accounting standard                     |                   |                   |                       | 104,244                 | 104,244              |
| Issuance of common stock                                | 606,395           | 6,064             | 5,043,939             | -                       | 5,050,003            |
| Warrant exercises                                       | 132,900           | 1,329             | 295,772               | -                       | 297,101              |
| Equity based compensation - employees                   | -                 | -                 | 1,800,225             | -                       | 1,800,225            |
| 401(k) contributions paid in common stock               | 4,474             | 45                | 40,892                | -                       | 40,937               |
| Stock issued to nonemployees for service                | 15,819            | 158               | 84,289                | -                       | 84,447               |
| Purchase of stock by officer                            | 3,725             | 37                | 24,963                | -                       | 25,000               |
| Share issuance costs                                    | -                 | -                 | (92,150)              | -                       | (92,150)             |
| Net loss  | -                 | -                 | -                     | (5,475,160)             | (5,475,160)          |
| <b>BALANCES AT DECEMBER 31, 2019</b>                    | <b>35,995,089</b> | <b>359,951</b>    | <b>365,705,533</b>    | <b>(359,097,170)</b>    | <b>6,968,314</b>     |
| Proceeds from the sale of common stock                  | 721,459           | 7,215             | 7,860,414             | -                       | 7,867,629            |
| Warrant exercises                                       | 562,100           | 5,621             | 4,313,085             | -                       | 4,318,706            |
| Equity based compensation - employees                   | -                 | -                 | 1,780,979             | -                       | 1,780,979            |
| 401(k) contributions paid in common stock               | 3,376             | 34                | 38,925                | -                       | 38,959               |
| Stock issued to nonemployees for service                | 17,120            | 171               | 234,853               | -                       | 235,024              |
| Purchase of stock by officers and directors             | 16,787            | 168               | 159,822               | -                       | 159,990              |
| Option exercises  | 20,480            | 205               | 49,693                | -                       | 49,898               |
| Share issuance costs                                    | -                 | -                 | (199,372)             | -                       | (199,372)            |
| Net loss  | -                 | -                 | -                     | (9,011,618)             | (9,011,618)          |
| <b>BALANCES AT MARCH 31, 2020</b>                       | <b>37,336,411</b> | <b>373,365</b>    | <b>379,943,932</b>    | <b>(368,108,788)</b>    | <b>12,208,509</b>    |
| Proceeds from the sale of common stock                  | 94,575            | 946               | 1,073,861             | -                       | 1,074,807            |
| Warrant exercises                                       | 849,845           | 8,498             | 10,147,777            | -                       | 10,156,275           |
| Equity based compensation - employees                   | -                 | -                 | 3,109,127             | -                       | 3,109,127            |
| 401(k) contributions paid in common stock               | 2,875             | 29                | 42,866                | -                       | 42,895               |
| Stock issued to nonemployees for service                | 14,811            | 148               | 205,233               | -                       | 205,381              |
| Shares issued for settlement of clinical research costs | 150,000           | 1,500             | 1,768,000             | -                       | 1,769,500            |
| Option exercises  | 73,719            | 737               | 275,678               | -                       | 276,415              |
| Modification of warrants                                | -                 | -                 | 5,554                 | -                       | 5,554                |
| Warrant issuances                                       | -                 | -                 | 805,753               | -                       | 805,753              |
| Share issuance costs                                    | -                 | -                 | (418,497)             | -                       | (418,497)            |
| Net loss  | -                 | -                 | -                     | (10,220,779)            | (10,220,779)         |
| <b>BALANCES AT JUNE 30, 2020</b>                        | <b>38,522,236</b> | <b>\$ 385,223</b> | <b>\$ 396,959,284</b> | <b>\$ (378,329,567)</b> | <b>\$ 19,014,940</b> |

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CEL-SCI CORPORATION  
STATEMENTS OF STOCKHOLDERS' EQUITY continued  
(UNAUDITED)

|   | Common<br>Shares | Stock<br>Amount | Additional<br>Paid-In<br>Capital | Accumulated<br>Deficit | Total        |
|---|------------------|-----------------|----------------------------------|------------------------|--------------|
| BALANCES AT OCTOBER 1, 2018                               | 28,034,487       | \$ 280,346      | \$ 331,312,184                   | \$ (331,591,614)       | \$ 916       |
| Warrant exercises   | 298,682          | 2,987           | 646,766                          |                        | 649,753      |
| 401(k) contributions paid in common stock                 | 12,279           | 123             | 35,118                           | -                      | 35,241       |
| Stock issued to nonemployees for service                  | 62,784           | 628             | 201,752                          | -                      | 202,380      |
| Shares returned for settlement of clinical research costs | (564,905)        | (5,649)         | 5,649                            | -                      | -            |
| Equity based compensation - employees                     | -                | -               | 573,660                          | -                      | 573,660      |
| Net income  | -                | -               | -                                | 1,245,902              | 1,245,902    |
| BALANCES AT DECEMBER 31, 2018                             | 27,843,327       | 278,435         | 332,775,129                      | (330,345,712)          | 2,707,852    |
| Warrant exercises   | 1,523,933        | 15,239          | 2,640,395                        | -                      | 2,655,634    |
| 401(k) contributions paid in common stock                 | 10,419           | 104             | 36,779                           | -                      | 36,883       |
| Stock issued to nonemployees for service                  | 77,449           | 774             | 224,855                          | -                      | 225,629      |
| Equity based compensation - employees                     | (3,500)          | (35)            | 530,865                          | -                      | 530,830      |
| Shares issued for settlement of clinical research costs   | 500,000          | 5,000           | 1,285,000                        | -                      | 1,290,000    |
| Share issuance costs                                      | -                | -               | (43,625)                         | -                      | (43,625)     |
| Net loss  | -                | -               | -                                | (6,447,681)            | (6,447,681)  |
| BALANCES AT MARCH 31, 2019                                | 29,951,628       | 299,517         | 337,449,398                      | (336,793,393)          | 955,522      |
| Warrant exercises   | 4,014,109        | 40,141          | 10,212,680                       | -                      | 10,252,821   |
| 401(k) contributions paid in common stock                 | 4,339            | 43              | 36,318                           | -                      | 36,361       |
| Stock issued to nonemployees for service                  | 20,825           | 208             | 140,062                          | -                      | 140,270      |
| Equity based compensation - employees                     | (4,000)          | (40)            | 1,521,861                        | -                      | 1,521,821    |
| Purchase of stock by officers and directors               | 37,243           | 372             | 234,625                          | -                      | 234,997      |
| Option exercises  | 42,770           | 428             | 96,862                           | -                      | 97,290       |
| Share issuance costs                                      | -                | -               | (8,010)                          | -                      | (8,010)      |
| Net loss  | -                | -               | -                                | (12,084,768)           | (12,084,768) |
| BALANCES AT JUNE 30, 2019                                 | 34,066,914       | \$ 340,669      | \$ 349,683,796                   | \$ (348,878,161)       | \$ 1,146,304 |

See notes to condensed financial statements.





CEL-SCI CORPORATION  
CONDENSED STATEMENTS OF CASH FLOWS  
NINE MONTHS ENDED JUNE 30, 2020 and 2019  
(UNAUDITED)

|  | <u>2020</u>          | <u>2019</u>         |
|--|----------------------|---------------------|
| Net loss   | \$ (24,707,557)      | \$ (17,286,547)     |
| Adjustments to reconcile net loss to<br>net cash used in operating activities: |                      |                     |
| Depreciation and amortization  | 1,442,255            | 513,028             |
| Share-based payments for services  | 623,146              | 688,070             |
| Equity based compensation  | 6,690,331            | 2,626,311           |
| Common stock contributed to 401(k) plan  | 122,791              | 108,485             |
| Shares issued for settlement of clinical research costs                        | 1,769,500            | 1,290,000           |
| Loss on derivative instruments   | 3,565,347            | 3,316,384           |
| Warrants inducement expense  | 805,753              | -                   |
| Warrant modification expense   | 5,554                | -                   |
| Capitalized lease interest   | -                    | 95,742              |
| (Increase)/decrease in assets:   |                      |                     |
| Receivables  | (192,242)            | 393                 |
| Prepaid expenses   | (969,219)            | 11,047              |
| Supplies used for R&D and manufacturing  | (4,648)              | (109,587)           |
| Increase/(decrease) in liabilities:  |                      |                     |
| Accounts payable   | (761,675)            | (3,567,182)         |
| Accrued expenses   | 87,820               | (113,280)           |
| Due to employees   | (166,310)            | (3,914)             |
| Other liabilities  | (815)                | (2,544)             |
|  | <u>(11,689,969)</u>  | <u>(12,433,594)</u> |
| Net cash used in operating activities  |                      |                     |
| CASH FLOWS FROM INVESTING ACTIVITIES:  |                      |                     |
| Purchases of property and equipment  | (1,530,327)          | (171,321)           |
| Expenditures for patent costs  | (39,975)             | (115,476)           |
|  | <u>(1,570,302)</u>   | <u>(286,797)</u>    |
| Net cash used in investing activities  |                      |                     |
| CASH FLOWS FROM FINANCING ACTIVITIES:  |                      |                     |
| Proceeds from issuance of common stock   | 13,992,439           | -                   |
| Payments of stock issuance costs   | (695,447)            | (90,224)            |
| Proceeds from the purchase of stock by officers and directors                  | 184,990              | 234,997             |
| Proceeds from exercises of warrants  | 11,736,757           | 11,657,590          |
| Proceeds from exercises of options   | 326,313              | 97,290              |
| Payments on obligations under finance lease                                    | (592,766)            | (3,811)             |
|  | <u>24,952,286</u>    | <u>11,895,842</u>   |
| Net cash provided by financing activities                                      |                      |                     |
| NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS                           | 11,692,015           | (824,549)           |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD                                 | <u>8,444,774</u>     | <u>10,310,044</u>   |
| CASH AND CASH EQUIVALENTS, END OF PERIOD                                       | <u>\$ 20,136,789</u> | <u>\$ 9,485,495</u> |

See notes to condensed financial statements.

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CEL-SCI CORPORATION  
CONDENSED STATEMENTS OF CASH FLOWS  
NINE MONTHS ENDED JUNE 30, 2020 and 2019

SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

|  | 2020         | 2019         |
|--|--------------|--------------|
| Property and equipment included in current liabilities         | \$ 121,441   | \$ -         |
| Capitalizable patent costs included in current liabilities     | \$ -         | \$ 30,000    |
| Right of use asset acquired and liability incurred             | \$ 399,032   | \$ -         |
| Finance lease obligation included in accounts payable          | \$ 775       | \$ 434       |
| Prepaid consulting services paid with issuance of common stock | \$ 11,706    | \$ (119,791) |
| Accrued consulting services to be paid with common stock       | \$ 110,000   | \$ -         |
| Fair value of warrant liabilities on date of exercise          | \$ 3,035,325 | \$ 1,900,618 |
| Stock issuance costs included in current liabilities           | \$ 30,152    | \$ 8,010     |
| Cash paid for interest   | \$ 872,710   | \$ 1,355,676 |



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**CEL-SCI CORPORATION**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**NINE MONTHS ENDED JUNE 30, 2020 AND 2019 (UNAUDITED)**

A. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed financial statements of CEL-SCI Corporation (the Company) are unaudited and certain information and footnote disclosures normally included in the annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) have been omitted pursuant to the rules and regulations of the Securities and Exchange Commission. While management of the Company believes that the disclosures presented are adequate to make the information presented not misleading, these interim condensed financial statements should be read in conjunction with the financial statements and notes included in the Company's annual report on Form 10-K/A for the year ended September 30, 2019.

In the opinion of management, the accompanying unaudited condensed financial statements contain all adjustments necessary for a fair presentation of the Company's financial position as of June 30, 2020 and the results of its operations for the nine and three months then ended. The condensed balance sheet as of September 30, 2019 is derived from the September 30, 2019 audited financial statements. On October 1, 2019, the Company adopted Accounting Standards Update (ASU) No. 2016-02, "Leases" and its related amendments (collectively referred to as Topic 842 and codified as Accounting Standards Codification 842, or ASC 842) using the modified retrospective transition approach. In accordance with this adoption method, results for the reporting period ended June 30, 2020 are presented under the new standard, while prior period results continue to be reported under the previous standard. All other significant accounting policies have been consistently applied in the interim financial statements and the annual financial statements. The results of operations for the nine and three months ended June 30, 2020 and 2019 are not necessarily indicative of the results to be expected for the entire year.

The financial statements have been prepared assuming the Company will continue as a going concern, but due to recurring losses from operations and the Company's necessity to continue to raise capital for future liquidity needs, raises substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Refer to discussion in Note B.

Summary of Significant Accounting Policies:

*Property Equipment* – Property and equipment is recorded at cost and depreciated using the straight-line method over estimated useful lives of five to seven years. Leasehold improvements are depreciated over the shorter of the estimated useful life of the asset or the term of

the lease. Repairs and maintenance which do not extend the life of the asset are expensed when incurred. The fixed assets are reviewed on a quarterly basis to determine if any of the assets are impaired.

*Patents* - Patent expenditures are capitalized and amortized using the straight-line method over the shorter of the expected useful life or the legal life of the patent (17 years). In the event changes in technology or other circumstances impair the value or life of the patent, appropriate adjustment in the asset value and period of amortization is made. An impairment loss is recognized when estimated future undiscounted cash flows expected to result from the use of the asset, and from its disposition, is less than the carrying value of the asset. The amount of the impairment loss would be the difference between the estimated fair value of the asset and its carrying value.

*Research and Development Costs* - Research and development costs are expensed as incurred. Management accrues Clinical Research Organization ("CRO") expenses and clinical trial study expenses based on services performed and relies on the CROs to provide estimates of those costs applicable to the completion stage of a study. Estimated accrued CRO costs are subject to revisions as such studies progress to completion. The Company charges revisions to estimated expense in the period in which the facts that give rise to the revision become known.

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*Income Taxes* - The Company uses the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating and tax loss carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company records a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be recognized. A full valuation allowance was recorded against the deferred tax assets as of June 30, 2020 and September 30, 2019.

*Derivative Instruments* – The Company has financing arrangements that consist of freestanding derivative instruments that contain embedded derivative features. The Company accounts for these arrangements in accordance with ASC 815, “*Accounting for Derivative Instruments and Hedging Activities*.” In accordance with ASC 815, derivative instruments and hybrid instruments are recognized as either assets or liabilities in the balance sheet and are measured at fair value with gains or losses recognized in earnings or other comprehensive income depending on the nature of the derivative or hybrid instruments. The Company determines the fair value of derivative instruments

and hybrid instruments based on available market data using appropriate valuation models considering all the rights and obligations of each instrument. The derivative liabilities are re-measured at fair value at the end of each interim period.

*Stock-Based Compensation* – Compensation cost for all stock-based awards is measured at fair value as of the grant date in accordance with the provisions of ASC 718 “*Compensation – Stock Compensation*.” The fair value of stock options is calculated using the Black-Scholes option pricing model. The Black-Scholes model requires various judgmental assumptions including volatility and expected option life. The stock-based compensation cost is recognized on the straight-line allocation method as expense over the requisite service or vesting period.

The Company has Incentive Stock Option Plans, Non-Qualified Stock Option Plans, Stock Compensation Plans, Stock Bonus Plans and an Incentive Stock Bonus Plan. In some cases, these Plans are collectively referred to as the “Plans”. All Plans have been approved by the Company’s stockholders.

The Company’s stock options are not transferable, and the actual value of the stock options that an employee may realize, if any, will depend on the excess of the market price on the date of exercise over the exercise price. The Company has based its assumption for stock price volatility on the variance of daily closing prices of the Company’s stock. The risk-free interest rate assumption was based on the U.S. Treasury rate at date of the grant with the term equal to the expected life of the option. Forfeitures are accounted for when they occur. The expected term of options represents the period that options granted are expected to be outstanding and has been determined based on an analysis of historical exercise behavior. If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation expense for new awards may differ materially in the future from that recorded in the current period.

Vesting of restricted stock granted under the Incentive Stock Bonus Plan is subject to service, performance and market conditions and meets the classification of equity awards. These awards were measured at market value on the grant-dates for issuances where the attainment of performance criteria is likely and at fair value on the grant-dates, using a Monte Carlo simulation for issuances where the attainment of performance criteria is uncertain. The total compensation cost will be expensed over the estimated requisite service period.

#### *Newly Adopted Accounting Pronouncements*

Effective October 1, 2019, the Company adopted ASC 842. ASC 842 requires that lessees recognize right-of-use assets and lease liabilities that are measured at the present value of the future lease payments at the lease commencement date. Subsequent measurement, including the presentation of expenses and cash flows, depends on the classification of the lease as either a finance lease or an operating lease. The Company elected the optional transition method that allows for a cumulative-effect adjustment in the period of adoption and did not restate prior periods. The Company also elected the transition package of three practical expedients which eliminates the requirements to reassess prior conclusions about lease identification, lease classification and initial direct costs. Further, the Company elected a short-term lease exception policy permitting the option to not apply the recognition requirements of this standard to short-term leases (i.e., leases with terms of 12 months or less) and an accounting policy to account for lease and non-lease components as a single component. The Company’s lease portfolio includes both finance and operating leases. The impact of adopting ASC 842 was to increase long term assets by approximately \$1.0 million, decrease total liabilities by approximately \$0.9 million and record a cumulative effect adjustment of approximately \$0.1 million to opening accumulated deficit.

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In June 2018, the Financial Accounting Standards Board (“FASB”) issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718)*, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees, and thus, the accounting for share-based payments to non-employees will be substantially aligned. The Company adopted ASU 2018-07 as of October 1, 2019 with no impact on its financial statements and related disclosures.

### *New Accounting Pronouncements*

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement - Disclosure Framework (Topic 820)*. The updated guidance improves the disclosure requirements on fair value measurements. The updated guidance becomes effective for the Company on October 1, 2021. Early adoption is permitted for any removed or modified disclosures. The Company is currently assessing the timing and impact of adopting the updated provisions.

The Company has considered all other recently issued accounting pronouncements and does not believe the adoption of such pronouncements will have a material impact on its financial statements.

## B. OPERATIONS AND FINANCING

On January 30, 2020, the World Health Organization (“WHO”) announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the “COVID-19 outbreak”) and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, because of the rapid increase in exposure globally, the WHO classified the COVID-19 outbreak as a pandemic. The full impact of the COVID-19 outbreak continues to evolve as of the date of this report. As such, it is uncertain as to the full magnitude that the pandemic will have on the Company’s financial condition, liquidity, and future results of operations. Management is actively monitoring the impact of the global situation on its financial condition, liquidity, operations, suppliers, industry, and workforce. Given the daily evolution of the COVID-19 outbreak and the global responses to curb its spread, the Company is not able to estimate the effects of the COVID-19 outbreak on its results of operations, financial condition, or liquidity for fiscal year 2020. Although the Company cannot estimate the length or gravity of the impact of the COVID-19 outbreak, if the pandemic continues, it may have an adverse effect on the Company’s results of future operations, financial position, and liquidity in fiscal year 2020.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief and Economic Security Act (CARES Act). The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions which are expected to impact the Company’s financial statements include removal of certain limitations on utilization of net operating losses, increasing the loss carryback period for certain losses to five years, and increasing the ability to deduct interest expense, as well as amending certain provisions of the previously enacted Tax Cuts and Jobs Act. The Company does not expect the enactment of the CARES Act to directly impact its financial position, results of operations or cash flows. The Company did not apply for a PPP loan under the CARES Act because it is able to access funds, if needed, in other ways.

On May 4, 2020, the Company announced that the pivotal Phase 3 head and neck cancer study of Multikine (Leukocyte Interleukin, Inj.) immunotherapy had reached the targeted threshold of 298 events (deaths) required to conduct the data evaluation. The Phase 3 study is

now in the phase that involves database lock and final analysis of the trial results. Given that the contract research organizations (CROs), not the Company, are running these activities and the uncertainties surrounding COVID-19 and its effect on various countries and their rules regarding travel and hospitals, the Company cannot give a reliable timeline. The Company will continue to remain blinded to the study results throughout this process. The Company will be advised of the results when the analysis is completed, and the study results will be announced to the public at that time.

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The Company has incurred significant costs since its inception for the acquisition of certain patented and unpatented proprietary technology and know-how relating to the human immunological defense system, patent applications, research and development, administrative costs, construction of laboratory facilities, and clinical trials. The Company has funded such costs with proceeds from loans and the public and private sale of its common stock. The Company will be required to raise additional capital or find additional long-term financing to continue with its research efforts. The ability to raise capital may be dependent upon market conditions that are outside the

control of the Company. The ability of the Company to complete the necessary clinical trials and obtain FDA approval for the sale of products to be developed on a commercial basis is uncertain. Ultimately, the Company must complete the development of its products, obtain the appropriate regulatory approvals and obtain sufficient revenues to support its cost structure. The Company believes there is a high likelihood that it will continue to receive funds from private and public offerings and warrant exercises similarly to the way it has substantially funded operations for the past 12 months. However, there can be no assurance that the Company will be able to raise sufficient capital to support its operations.

The Company is currently in the final stages of its large multi-national Phase 3 clinical trial for head and neck cancer with its partners TEVA Pharmaceuticals and Orient Europharma. To finance the study beyond the next twelve months, the Company plans to raise additional capital in the form of corporate partnerships, warrant exercises, debt issuances and/or equity financings. The Company believes that it will be able to obtain additional financing because it has done so consistently in the past and because Multikine is a product in the Phase 3 clinical trial stage. However, there can be no assurance that the Company will be successful in raising additional funds on a timely basis or that the funds will be available to the Company on acceptable terms or at all. If the Company does not raise the necessary amounts of money, it may have to curtail its operations until it can raise the required funding.

The financial statements have been prepared assuming the Company will continue as a going concern, but due to the Company's recurring losses from operations and future liquidity needs, there is substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

C. STOCKHOLDERS' EQUITY

*Proceeds from the Sale of Common Stock*

In March 2020, the Company sold 630,500 shares of common stock at a public offering price of \$12.22 per share and received aggregate net proceeds of approximately \$7.1 million. Under the terms of the Underwriting Agreement the Company granted the Underwriters a 45-day option to purchase up to an additional 94,575 shares of common stock solely to cover over-allotments. The underwriter fully exercised this option in May 2020 resulting in additional net proceeds to the Company of approximately \$1.1 million.

In December 2019, the Company sold 606,395 shares of common stock at a public offering price of \$9.07 per share and received aggregate net proceeds of approximately \$5.0 million. In January 2020, the underwriters of that offering fully exercised the option to purchase 90,959 additional shares of common stock at the public offering price of \$9.07 per share for aggregate net proceeds to the Company of approximately \$0.8 million.



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*Equity Compensation*

Underlying share information for equity compensation plans as of June 30, 2020 is as follows:

| <b>Name of Plan</b>              | <b>Total Shares Reserved Under Plans</b> | <b>Shares Reserved for Outstanding Options</b> | <b>Shares Issued</b> | <b>Remaining Options/Shares Under Plans</b> |
|----------------------------------|--|--|----------------------|---|
| Incentive Stock Options Plans    | 138,400                                  | 89,895   | N/A                  | 213   |
| Non-Qualified Stock Option Plans | 9,987,200                                | 8,593,438                                      | N/A                  | 1,151,666                                   |
| Stock Bonus Plans                | 783,760                                  | N/A  | 341,951              | 441,776                                     |
| Stock Compensation Plans         | 634,000                                  | N/A  | 150,695              | 464,895                                     |
| Incentive Stock Bonus Plan       | 640,000                                  | N/A  | 616,500              | 23,500                                      |

Underlying share information for equity compensation plans as of September 30, 2019 is as follows:

| <b>Name of Plan</b>              | <b>Total Shares Reserved Under Plans</b> | <b>Shares Reserved for Outstanding Options</b> | <b>Shares Issued</b> | <b>Remaining Options/Shares Under Plans</b> |
|----------------------------------|--|--|----------------------|---|
| Incentive Stock Option Plans     | 138,400                                  | 89,895   | N/A                  | 213   |
| Non-Qualified Stock Option Plans | 6,387,200                                | 6,128,321                                      | N/A                  | 112,166                                     |
| Stock Bonus Plans                | 783,760                                  | N/A  | 331,226              | 452,501                                     |
| Stock Compensation Plans         | 634,000                                  | N/A  | 130,183              | 485,407                                     |
| Incentive Stock Bonus Plan       | 640,000                                  | N/A  | 616,500              | 23,500                                      |

Stock option activity:

|           | <b>Nine Months Ended June 30,</b> |             |
|-----------|-----------------------------------|-------------|
|           | <b>2020</b>                       | <b>2019</b> |
| Granted   | 2,561,500                         | 3,268,862   |
| Exercised | 94,199                            | 42,770      |
| Expired   | 1,000                             | 29,322      |
| Forfeited | 1,180                             | 63,698      |

|           | Three Months Ended June 30, |           |
|-----------|-----------------------------|-----------|
|           | 2020                        | 2019      |
| Granted   | 2,559,000                   | 3,268,362 |
| Exercised | 73,719                      | 42,770    |
| Expired   | 16                          | 26,922    |
| Forfeited | -                           | 39,505    |

During the quarter ended June 30, 2020, the Company adopted the 2020 Non-Qualified Stock Option Plan, which provides for the issuance of up to 3,600,000 options to purchase shares of common stock. On April 20, 2020, the Company granted 1,872,000 performance-based stock options from the 2020 Non-Qualified Stock Option Plan to officers and directors. Each option entitles the holder to purchase one share of the Company's common stock at a price of \$10.93 per share, the fair value on the date of issuance. The stock options vest upon the achievement of the following performance goals: i) 25% of the options will vest when the closing price of the Company's common stock exceeds \$20.00 for ten consecutive trading days; ii) 50% of the options will vest when the closing price of the Company's common stock exceeds \$25.00 for ten consecutive trading days; iii) 75% of the options will vest when the closing price of the Company's common stock exceeds \$30.00 for ten consecutive trading days; and iv) 100% of the options will vest when either (a) the filing of the first marketing application for any pharmaceutical based upon the Company's Multikine technology, in the US, Canada, UK, Germany, France, Italy, Spain, Japan, or Australia or (b) the closing price of the Company's common stock exceeds \$40.00 for ten consecutive trading days. All Options which have not vested as of April 19, 2030, will be canceled and will no longer be exercisable. The options were recorded as equity based warrants in accordance with ASC 718, Compensation – Stock Compensation. On the grant date, the options were valued using a Monte Carlo Simulation approach. Monte Carlo Simulation is a statistical technique that is used to model probabilistic systems and establish the probabilities for a variety of outcomes. That valuation resulted in a per share fair value of \$4.12 and an aggregate value of \$7,881,120 on the grant date, April 20, 2020. The aggregate value will be expensed over the implicit life of the options, which was determined to be 1.7 years. This resulted in compensation expense of approximately \$901,000 recorded during the nine and three months ended June 30, 2020.

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Stock-Based Compensation Expense

|               | Nine months Ended June 30, |              |
|---------------|----------------------------|--------------|
|               | 2020                       | 2019         |
| Employees     | \$ 6,690,331               | \$ 2,626,311 |
| Non-employees | \$ 623,146                 | \$ 688,070   |

  

|               | Three months Ended June 30, |              |
|---------------|-----------------------------|--------------|
|               | 2020                        | 2019         |
| Employees     | \$ 3,109,127                | \$ 1,521,821 |
| Non-employees | \$ 275,919                  | \$ 176,646   |

Employee compensation expense includes the expense related to options issued or vested and restricted stock granted. Non-employee expense includes the expense related to options and stock issued to consultants expensed over the period of their service contracts.

*Warrants and Non-Employee Options*

The following chart represents the warrants and non-employee options outstanding at June 30, 2020:

| Warrant/Options | Issue Date | Shares Issuable upon Exercise of Warrants/<br>Options | Exercise Price | Expiration Date | Reference |
|-----------------|------------|---|----------------|-----------------|-----------|
| Series N        | 8/18/2008  | 85,339  | \$ 3.00        | 2/18/2021       | 2         |

|             |            |         |    |       |            |   |
|-------------|------------|---------|----|-------|------------|---|
| Series XX   | 6/11/2020  | 461,953 | \$ | 18.00 | 9/10/2020  | 2 |
| Series YY   | 6/26/2020  | 101,839 | \$ | 20.00 | 9/25/2020  | 2 |
| Series UU   | 6/11/2018  | 93,603  | \$ | 2.80  | 12/31/2020 | 2 |
| Series W    | 10/28/2015 | 688,930 | \$ | 16.75 | 10/28/2020 | 1 |
| Series X    | 1/13/2016  | 120,000 | \$ | 9.25  | 1/13/2021  | * |
| Series Y    | 2/15/2016  | 26,000  | \$ | 12.00 | 2/15/2021  | * |
| Series ZZ   | 5/23/2016  | 20,000  | \$ | 13.75 | 5/18/2021  | 1 |
| Series BB   | 8/26/2016  | 16,000  | \$ | 13.75 | 8/22/2021  | 1 |
| Series Z    | 5/23/2016  | 264,000 | \$ | 13.75 | 11/23/2021 | 1 |
| Series CC   | 12/8/2016  | 153,643 | \$ | 5.00  | 12/8/2021  | 1 |
| Series HH   | 2/23/2017  | 200     | \$ | 3.13  | 2/16/2022  | 1 |
| Series AA   | 8/26/2016  | 200,000 | \$ | 13.75 | 2/22/2022  | 1 |
| Series MM   | 6/22/2017  | 893,491 | \$ | 1.86  | 6/22/2022  | * |
| Series NN   | 7/24/2017  | 375,545 | \$ | 2.52  | 7/24/2022  | 2 |
| Series OO   | 7/31/2017  | -       | \$ | 2.52  | 7/31/2022  | 2 |
| Series RR   | 10/30/2017 | 457,116 | \$ | 1.65  | 10/30/2022 | 2 |
| Series SS   | 12/19/2017 | 326,064 | \$ | 2.09  | 12/18/2022 | 2 |
| Series TT   | 2/5/2018   | 371,564 | \$ | 2.24  | 2/5/2023   | 2 |
| Series VV   | 7/2/2018   | -       | \$ | 1.75  | 1/2/2024   | 2 |
| Consultants | 7/28/17    | 10,000  | \$ | 2.18  | 7/27/2027  | * |

\* No current period changes to these warrants and non-employee options.

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1. Warrant Liabilities

The table below presents the fair value of the warrant liabilities at the balance sheet dates:

|                           | June 30,<br>2020    | September 30,<br>2019 |
|---------------------------|---------------------|-----------------------|
| Series V warrants         | \$ -                | \$ 674,442            |
| Series W warrants         | 1,808,203           | 1,193,507             |
| Series Z warrants         | 1,852,040           | 1,109,545             |
| Series ZZ warrants        | 115,957             | 77,638                |
| Series AA warrants        | 1,464,362           | 916,908               |
| Series BB warrants        | 108,586             | 63,966                |
| Series CC warrants        | 1,666,749           | 1,710,898             |
| Series FF warrants        | -                   | 446,185               |
| Series HH warrants        | 2,435               | 45,657                |
| Series JJ warrants        | -                   | 66,599                |
| Series LL warrants        | -                   | 182,965               |
| Total warrant liabilities | <u>\$ 7,018,332</u> | <u>\$ 6,488,310</u>   |

The table below presents the gains/(losses) on the warrant liabilities for the nine months ended June 30:

|                                 | 2020                  | 2019                  |
|---------------------------------|-----------------------|-----------------------|
| Series S warrants               | \$ -                  | \$ 33                 |
| Series V warrants               | 185,652               | (479,399)             |
| Series W warrants               | (614,696)             | (1,132,156)           |
| Series Z warrants               | (742,495)             | (684,859)             |
| Series ZZ warrants              | (38,319)              | (37,970)              |
| Series AA warrants              | (547,454)             | (583,516)             |
| Series BB warrants              | (44,620)              | (35,800)              |
| Series CC warrants              | (1,245,627)           | (2,007,287)           |
| Series DD warrants              | -                     | 1,249,287             |
| Series EE warrants              | -                     | 1,249,287             |
| Series FF warrants              | (319,706)             | (244,170)             |
| Series GG warrants              | -                     | 195,228               |
| Series HH warrants              | (35,024)              | (22,859)              |
| Series II warrants              | -                     | (593,960)             |
| Series JJ warrants              | (64,992)              | (32,954)              |
| Series KK warrants              | -                     | (55,622)              |
| Series LL warrants              | (98,066)              | (99,667)              |
| Net loss on warrant liabilities | <u>\$ (3,565,347)</u> | <u>\$ (3,316,384)</u> |

The table below presents the gains/(losses) on the warrant liabilities for the three months ended June 30:

|                                 | 2020                  | 2019                  |
|---------------------------------|-----------------------|-----------------------|
| Series V warrants               | \$ 107,191            | \$ (974,251)          |
| Series W warrants               | (247,327)             | (1,748,184)           |
| Series Z warrants               | (430,619)             | (799,690)             |
| Series ZZ warrants              | (33,734)              | (50,608)              |
| Series AA warrants              | (220,831)             | (676,784)             |
| Series BB warrants              | (37,592)              | (43,536)              |
| Series CC warrants              | (419,350)             | (2,346,985)           |
| Series FF warrants              | -                     | (278,773)             |
| Series GG warrants              | -                     | 88,478                |
| Series HH warrants              | (567)                 | (33,501)              |
| Series II warrants              | -                     | (709,303)             |
| Series JJ warrants              | -                     | (48,880)              |
| Series KK warrants              | -                     | (169,089)             |
| Series LL warrants              | -                     | (114,413)             |
| Net loss on warrant liabilities | <u>\$ (1,282,829)</u> | <u>\$ (7,905,519)</u> |

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The Company reviews all outstanding warrants in accordance with the requirements of ASC 815. This topic provides that an entity should use a two-step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. The warrant agreements provide for adjustments to the exercise price for certain dilutive events. Under the provisions of ASC 815, the warrants are not considered indexed to the Company's stock because future equity offerings or sales of the Company's stock are not an input to the fair value of a "fixed-for-fixed" option on equity shares, and equity classification is therefore precluded.

In accordance with ASC 815, derivative liabilities must be measured at fair value upon issuance and re-valued at the end of each reporting period through expiration. Any change in fair value between the respective reporting dates is recognized as a gain or loss.

### *Changes in Warrant Liabilities*

On May 26, 2020, the Company lowered the exercise price of 810,127 Series V warrants from \$19.75 to \$13.75 per share and extended the expiration date of the Series V warrants from May 28, 2020 to June 25, 2020. The incremental cost of this modification was approximately \$664,000, which was included within the net loss on derivatives for the nine and three months ended June 30, 2020. Additionally, upon the exercise of 674,164 Series V warrants the Company recognized a final mark-to-market adjustment for a gain of approximately \$560,000, which was included within the net loss on derivatives for the nine and three months ended June 30, 2020.

On June 25, 2020, 135,963 Series V warrants, with an exercise price of \$13.75 expired. The warrants were valued at approximately \$211,000 on the date of expiration.

On December 10, 2018, 1,360,960 Series DD and 1,360,960 Series EE warrants, with an exercise price of \$4.50 expired.

On October 11, 2018, 327,729 Series S warrants, with an exercise price of \$31.25 expired.

### *Exercise of Warrant Liabilities*

The following warrants recorded as liabilities were exercised during the periods ended June 30, 2020.

| Warrants  | Three Months       |                |             | Nine Months        |                |              |
|-----------|--------------------|----------------|-------------|--------------------|----------------|--------------|
|           | Warrants Exercised | Exercise Price | Proceeds    | Warrants Exercised | Exercise Price | Proceeds     |
| Series V  | 674,164            | \$ 13.75       | \$9,269,755 | 674,164            | \$ 13.75       | \$ 9,269,755 |
| Series CC | -                  | -              | -           | 123,820            | \$ 5.00        | 619,100      |
| Series FF | -                  | -              | -           | 68,048             | \$ 3.91        | 265,812      |
| Series HH | -                  | -              | -           | 6,300              | \$ 3.13        | 19,687       |
| Series JJ | -                  | -              | -           | 9,450              | \$ 3.13        | 29,531       |

|           |                |   |                    |                |    |      |                     |
|-----------|----------------|---|--------------------|----------------|----|------|---------------------|
| Series LL | -              | - | -                  | 26,398         | \$ | 3.59 | 94,867              |
|           | <u>674,164</u> |   | <u>\$9,269,755</u> | <u>908,180</u> |    |      | <u>\$10,298,752</u> |



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The following warrants recorded as liabilities were exercised during the periods ended June 30, 2019.

**Three Months**

**Nine Months**

| Warrants  | Exercise           |         |                    | Exercise           |         |                    |
|-----------|--------------------|---------|--------------------|--------------------|---------|--------------------|
|           | Warrants Exercised | Price   | Proceeds           | Warrants Exercised | Price   | Proceeds           |
| Series CC | 69,017             | \$ 5.00 | \$ 345,085         | 69,017             | \$ 5.00 | \$ 345,085         |
| Series GG | 200,000            | \$ 3.00 | 600,000            | 200,000            | \$ 3.00 | 600,000            |
| Series HH | 13,500             | \$ 3.13 | 42,188             | 13,500             | \$ 3.13 | 42,188             |
| Series II | 121,500            | \$ 3.00 | 364,500            | 121,500            | \$ 3.00 | 364,500            |
| Series JJ | 20,550             | \$ 3.13 | 64,219             | 20,550             | \$ 3.13 | 64,219             |
| Series KK | 213,870            | \$ 3.04 | 649,095            | 213,870            | \$ 3.04 | 649,095            |
|           | <u>638,437</u>     |         | <u>\$2,065,087</u> | <u>638,437</u>     |         | <u>\$2,065,087</u> |

2. Equity Warrants

*Changes in Equity Warrants*

On May 26, 2020, the Company provided that for each Series V warrant exercised by an accredited investor on or before June 10, 2020 the former holder of the Series V warrant received one Series XX warrant. Every Series XX warrant will allow the holder to purchase one share of the Company's common stock at a price of \$18.00 per share at any time on or before September 10, 2020. For every two Series V warrant exercised by an accredited investor after June 10, 2020 but on or before June 25, 2020 the former holder of the Series V warrant received one Series YY warrant. Every Series YY warrants will allow the holder to purchase one share of the Company's common stock at a price of \$20.00 per share at any time on or before September 25, 2020. In June 2020, 461,953 Series XX warrants and 101,839 Series YY warrants were issued to the former holders of the Series V warrants. The Company recognized an inducement expense equal to the fair value of the Series XX and Series YY warrants issued as of the date the inducement offers were accepted. The fair values of the Series XX and Series YY warrants were calculated to be approximately \$629,000 and \$177,000, respectively, and are included as inducement expense in the statements of operations for the nine and three months ended June 30, 2020. The Series XX and YY warrants qualify for equity treatment in accordance with ASC 815.

On May 8, 2020, the expiration date of 93,593 Series UU warrants were extended from June 11, 2020 to December 31, 2020. These warrants were previously issued as an inducement to convert notes payable into shares of common stock. The incremental cost of this extension was approximately \$6,000 and was recorded as interest expense for the nine and three months ended June 30, 2020. The Series UU warrants are held by Geert Kersten, Patricia Prichep (current Officers of the Company) and the de Clara Trust, of which the Company's CEO, Geert Kersten, is a beneficiary.

On January 23, 2020, the expiration date of the Series N warrants was extended to February 18, 2021. The incremental cost of this extension was approximately \$22,000, which was recorded as a deemed dividend in the financial statements for the nine and three months ended June 30, 2020. The Series N warrants are held by the de Clara Trust, of which Geert Kersten, is a beneficiary.

*Exercise of Equity Warrants*

The following warrants recorded as equity were exercised during the periods ended June 30, 2020.

| Warrants  | Three Months       |                |                   | Nine Months        |                |                    |
|-----------|--------------------|----------------|-------------------|--------------------|----------------|--------------------|
|           | Warrants Exercised | Exercise Price | Proceeds          | Warrants Exercised | Exercise Price | Proceeds           |
| Series NN | -                  | -              | \$ -              | 98,253             | \$ 2.52        | \$ 247,598         |
| Series OO | 10,000             | \$ 2.52        | 25,200            | 50,000             | \$ 2.52        | 126,000            |
| Series SS | 39,474             | \$ 2.09        | 82,500            | 156,580            | \$ 2.09        | 327,252            |
| Series TT | 10,000             | \$ 2.24        | 22,400            | 188,125            | \$ 2.24        | 421,400            |
| Series UU | 61,207             | \$ 2.80        | 171,380           | 61,207             | \$ 2.80        | 171,380            |
| Series VV | 55,000             | \$ 1.75        | 96,250            | 82,500             | \$ 1.75        | 144,375            |
|           | <u>175,681</u>     |                | <u>\$ 397,730</u> | <u>636,665</u>     |                | <u>\$1,438,005</u> |

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The following warrants recorded as equity were exercised during the periods ended June 30, 2019.

| Warrants  | Three Months       |                |                    | Nine Months        |                |                    |
|-----------|--------------------|----------------|--------------------|--------------------|----------------|--------------------|
|           | Warrants Exercised | Exercise Price | Proceeds           | Warrants Exercised | Exercise Price | Proceeds           |
| Series NN | 65,502             | \$ 2.52        | \$ 165,065         | 65,502             | \$ 2.52        | \$ 165,065         |
| Series PP | -                  | -              | -                  | 60,000             | \$ 2.30        | 138,000            |
| Series QQ | 3,500              | \$ 2.50        | 8,750              | 3,500              | \$ 2.50        | 8,750              |
| Series RR | 60,044             | \$ 1.65        | 99,073             | 60,044             | \$ 1.65        | 99,073             |
| Series SS | 280,264            | \$ 2.09        | 585,752            | 446,054            | \$ 2.09        | 932,253            |
| Series TT | 450,069            | \$ 2.24        | 1,008,155          | 536,119            | \$ 2.24        | 1,200,907          |
| Series UU | 24,018             | \$ 2.80        | 67,250             | 24,018             | \$ 2.80        | 67,250             |
| Series VV | 2,425,000          | \$ 1.75        | 4,243,750          | 3,810,000          | \$ 1.75        | 6,667,500          |
| Series WW | 67,275             | \$ 1.63        | 109,321            | 193,050            | \$ 1.63        | 313,705            |
|           | <u>3,375,672</u>   |                | <u>\$6,287,116</u> | <u>5,198,287</u>   |                | <u>\$9,592,503</u> |

3. Options and Shares Issued to Consultants

During the nine months ended June 30, 2020 and 2019, the Company issued 47,750 and 161,058 shares, respectively, of restricted common stock to consultants for services. The weighted average grant date fair value of the shares issued to consultants was \$11.60 and \$3.37, respectively, during the nine months ended June 30, 2020 and 2019, respectively. During the three months ended June 30, 2020 and 2019, the Company issued 14,811 and 20,825, respectively, shares of restricted common stock to consultants for services. The weighted average grant date fair value of the shares issued to consultants was \$16.41 and \$5.62, respectively, during the three months ended June 30, 2020 and 2019. The aggregate values of the issuances of restricted common stock and common stock options are recorded as prepaid expenses and are charged to general and administrative expenses over the periods of service under the consulting arrangements.

During the nine months ended June 30, 2020 and 2019, the Company recorded total expense of approximately \$623,000 and \$688,000, respectively, relating to these consulting agreements. During the three months ended June 30, 2020 and 2019, the Company recorded total expense of approximately \$276,000 and \$177,000, respectively, relating to these consulting agreements. At June 30, 2020 and September 30, 2019, approximately \$242,000 and \$230,000, respectively, are included in prepaid expenses. At June 30, 2020, the Company has accrued \$110,000 for shares to be issued. As of June 30, 2020, 10,000 options issued to consultants remained outstanding, all of which were issued from the Non-Qualified Stock Option plans and are fully vested.

4. Securities Purchase Agreement

The Company has entered into Securities Purchase Agreements (SPA) with Ergomed plc, one of the Company's Clinical Research Organizations responsible for managing the Company's Phase 3 clinical trial, to facilitate payment of amounts due Ergomed. Under the Agreements, the Company issued Ergomed shares of common stock and the net proceeds from the sales of those shares reduces outstanding amounts due Ergomed. Upon issuance, the Company expenses the full value of the shares as Other non-operating gain/loss and subsequently offsets the expense as amounts are realized through the sale by Ergomed and reduces accounts payable to Ergomed.

On April 6, 2020 and June 29, 2020, the Company entered SPAs under which it issued Ergomed 100,000 and 50,000 restricted shares of the Company's common stock valued at approximately \$1.0 million and \$0.8 million, respectively.

On January 9, 2019, the Company entered into a SPA under which it issued Ergomed 500,000 restricted shares of the Company's common stock valued at approximately \$1.3 million.

As of June 30, 2020, Ergomed held 110,521 shares for resale.





The following table summarizes the Other non-operating gain (loss) for the nine and three months ended June 30, 2020 and 2019 relating to these agreements:

|  | Nine Months Ended |               | Three Months Ended |               |
|--|-------------------|---------------|--------------------|---------------|
|  | June 30, 2020     | June 30, 2019 | June 30, 2020      | June 30, 2019 |
| Amount realized through the resale of shares | \$ 2,539,245      | \$ 3,167,197  | \$ 818,565         | \$ 1,455,844  |
| Fair value of shares upon issuance           | 1,769,500         | 1,290,000     | 1,769,500          | -             |
| Other non-operating gain (loss)              | \$ 769,745        | \$ 1,877,197  | \$ (950,935)       | \$ 1,455,844  |

D. FAIR VALUE MEASUREMENTS

In accordance with ASC 820-10, “Fair Value Measurements,” the Company determines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company generally applies the income approach to determine fair value. This method uses valuation techniques to convert future amounts to a single present amount. The measurement is based on the value indicated by current market expectations with respect to those future amounts.

ASC 820-10 establishes a fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to active markets for identical assets and liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement). The Company classifies fair value balances based on the observability of those inputs. The three levels of the fair value hierarchy are as follows:

- Level 1 – Observable inputs such as quoted prices in active markets for identical assets or liabilities
- Level 2 – Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and amounts derived from valuation models where all significant inputs are observable in active markets
- Level 3 – Unobservable inputs that reflect management’s assumptions

For disclosure purposes, assets and liabilities are classified in their entirety in the fair value hierarchy level based on the lowest level of input that is significant to the overall fair value measurement. The Company’s assessment of the significance of an input to the fair value measurement requires judgment and may affect the placement within the fair value hierarchy levels.

The table below sets forth the assets and liabilities measured at fair value on a recurring basis, by input level, in the condensed balance sheet at June 30, 2020:

|                        | Quoted Prices in<br>Active Markets for<br>Identical Assets or<br>Liabilities<br>(Level 1) | Significant Other<br>Observable Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) | Total        |
|------------------------|---|---|--|--------------|
| Derivative instruments | \$ -  | \$ -  | \$ 7,018,332                                       | \$ 7,018,332 |

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The table below sets forth the assets and liabilities measured at fair value on a recurring basis, by input level, in the condensed balance sheet at September 30, 2019:

|                        | Quoted Prices in<br>Active Markets for<br>Identical Assets or<br>Liabilities<br>(Level 1) | Significant Other<br>Observable Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) | Total        |
|------------------------|---|---|--|--------------|
| Derivative instruments | \$ -  | \$ -  | \$ 6,488,310                                       | \$ 6,488,310 |

The following sets forth the reconciliation of beginning and ending balances related to fair value measurements using significant unobservable inputs (Level 3) for the three months ended June 30, 2020 and the year ended September 30, 2019:

|                                | Nine<br>months<br>ended<br>June 30,<br>2020 | Twelve<br>months<br>ended<br>September<br>30, 2019 |
|--------------------------------|---|--|
| Beginning balance              | \$ 6,488,310                                | \$ 9,317,031                                       |
| Issuances                      | -   | -  |
| Exercises                      | (3,035,325)                                 | (3,589,357)  |
| Realized and unrealized losses | 3,565,347                                   | 760,636  |
| Ending balance                 | <u>\$ 7,018,332</u>                         | <u>\$ 6,488,310</u>                                |

The fair values of the Company's derivative instruments disclosed above under Level 3 are primarily derived from valuation models where significant inputs such as historical price and volatility of the Company's stock, as well as U.S. Treasury Bill rates, are observable in active markets.

E. RELATED PARTY TRANSACTIONS

During the nine months ended June 30, 2020, officers and directors of the Company purchased 20,512 shares of restricted common stock at an aggregate fair market value of approximately \$185,000. No shares were purchased during the three months ended June 30, 2020.

On May 8, 2020, the expiration date of 93,593 Series UU warrants were extended from June 11, 2020 to December 31, 2020. The incremental cost of this extension was approximately \$6,000 and was recorded as interest expense for the nine and three months ended June 30, 2020.

On January 23, 2020, the expiration date of the Series N warrants was extended to February 18, 2021. The incremental cost of this extension was approximately \$22,000, which was recorded as a deemed dividend in the financial statements for the nine and three months ended June 30, 2020. The Series N warrants are held by the de Clara Trust.

F. COMMITMENTS AND CONTINGENCIES

*Clinical Research Agreements*

Under co-development and revenue sharing agreements with Ergomed, Ergomed agreed to contribute up to \$12 million towards the Company's Phase 3 Clinical Trial in the form of discounted clinical services in exchange for a single digit percentage of milestone and royalty payments, up to a specific maximum amount. The Company accounted for the co-development and revenue sharing agreements in accordance with ASC 808 "Collaborative Arrangements". The Company determined the payments to Ergomed are within the scope of ASC 730 "Research and Development." Therefore, the Company records the discount on the clinical services as a credit to research and development expense on its Statements of Operations. Since the inception of the agreement with Ergomed, the Company has incurred research and development expenses of approximately \$32.7 million for Ergomed's services. This amount is net of Ergomed's discount of approximately \$10.8 million. During the nine months ended June 30, 2020 and 2019, the Company recorded, net of Ergomed's discount, approximately \$1.3 million and \$2.2 million, respectively, as research and development expense related to Ergomed's services.



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*Lease Agreements*

The Company determines whether a contract contains a lease at the inception of a contract by determining if the contract conveys the right to control the use of identified property, plant or equipment over a period of time in exchange for consideration. The Company leases certain real estate, machinery, equipment and office equipment for varying periods. Many of these leases include an option to either renew or terminate the lease. For purposes of calculating lease liabilities, these options are included in the lease term when it is reasonably certain that the Company will exercise such options. The incremental borrowing rate utilized to calculate the lease liabilities is based on the information available at commencement date, as most of the leases do not provide an implicit borrowing rate. Short-term leases, defined as leases with initial terms of 12 months or less, are not reflected on the balance sheet. Lease expense for such short-term leases is not material. For purposes of calculating lease liabilities, lease and non-lease components are combined.

The Company leases a manufacturing facility near Baltimore, Maryland (the San Tomas lease). The building was remodeled in accordance with the Company's specifications so that it can be used by the Company to manufacture Multikine for the Company's Phase 3 clinical trial and sales of the drug if approved by the FDA. The lease is for a term of twenty years and requires annual base rent to escalate each year at 3%. The Company is required to pay all real estate and personal property taxes, insurance premiums, maintenance expenses, repair costs and utilities. The lease allows the Company, at its election, to extend the lease for two ten-year periods or to purchase the building at the end of the 20-year lease, which expires in October 2028.

Upon adoption of ASC 842 on October 1, 2019, the Company recorded a finance lease right of use asset and a finance lease liability of approximately \$13.5 million. As of June 30, 2020, the net book value of the finance lease right of use asset is approximately \$12.4 million and the balance of the finance lease liability is approximately \$12.9 million, of which approximately \$0.9 million is current. These amounts include the San Tomas lease as well as several other smaller finance leases for office equipment. The finance right of use assets are being depreciated using a straight-line method over the underlying lease terms. Total cash paid related to finance leases during the nine months ended June 30, 2020 was approximately \$1,414,000, of which approximately \$873,000 was for interest. The weighted average discount rate of the Company's finance leases is 8.8% and the weighted average time to maturity is 8.3 years.

The Company was required to deposit the equivalent of one year of base rent in accordance with the lease. When the Company meets the minimum cash balance required by the lease, the deposit will be returned to the Company. The approximate \$1.7 million deposit is included in non-current assets at June 30, 2020 and September 30, 2019.

Approximate future minimum lease payments under finance leases as of June 30, 2020 are as follows:

|  |                      |
|--|----------------------|
| Three months ending September 30, 2020               | \$ 473,000           |
| Year ending September 30,                            |                      |
| 2021   | 1,953,000            |
| 2022   | 2,014,000            |
| 2023   | 2,083,000            |
| 2024   | 2,148,000            |
| 2025   | 2,218,000            |
| Thereafter   | 7,322,000            |
| Total future minimum lease obligation                | 18,211,000           |
| Less imputed interest on finance lease obligations   | (5,316,000)          |
| Net present value of lease finance lease obligations | <u>\$ 12,895,000</u> |

Effective April 30, 2020, the Company terminated a month-to-month arrangement with a sub-lessee as the sub-leased space is needed to prepare the facility to produce Multikine for commercial purposes and before the Company's Biologics License Application (BLA) can be submitted to the FDA. The sublease rental income for the nine and three months ended June 30, 2020 was approximately \$39,000 and \$2,000, respectively. The sublease rental income for the nine and three months ended June 30, 2019 was approximately \$55,000 and \$18,000, respectively.

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The Company leases two facilities under 60-month operating leases – the lease for its research and development laboratory expires February 28, 2022 and the lease for its office headquarters expired on June 30, 2020. The office headquarter lease was renewed on July 1, 2020 and will expire on November 30, 2025. During the nine months ended June 30, 2020, the Company incurred approximately \$80,000 in leasehold improvements costs for the research and development lab and is reasonably certain to renew the lease through February 28, 2027. The renewal period is included in the right of use asset and liability calculations. The operating leases include escalating rental payments. The Company is recognizing the related rent expense on a straight-line basis over the full 60-month terms of the leases. Upon adoption of ASC 842 on October 1, 2019, the Company recorded an operating lease right of use asset and an operating lease liability of approximately \$1.0 million. As of June 30, 2020, the net book value of the operating lease right of use asset is approximately \$1.2 million and the balance of the operating lease liability is approximately \$1.3 million, of which approximately \$0.1 million is current. The Company incurred lease expense under operating leases of approximately \$202,000 and \$67,000 for the nine and three months ended June 30, 2020, respectively. Total cash paid related to operating leases during the nine and three months ended June 30, 2020 was approximately \$198,000 and \$66,000, respectively.

As of June 30, 2020, future minimum lease payments on operating leases are as follows:

|   |                     |
|---|---------------------|
| Three months ending September 30, 2020              | \$ 40,000           |
| Year ending September 30,                           |                     |
| 2021  | 241,000             |
| 2022  | 264,000             |
| 2023  | 272,000             |
| 2024  | 280,000             |
| 2025  | 288,000             |
| Thereafter  | 286,000             |
| Total future minimum lease obligation               | 1,671,000           |
| Less imputed interest on operating lease obligation | (409,000)           |
| Net present value of operating lease obligation     | <u>\$ 1,262,000</u> |

G. PATENTS

During the nine months ended June 30, 2020 and 2019, no patent impairment charges were recorded. For the nine months ended June 30, 2020 and 2019, amortization of patent costs totaled approximately \$40,000 and \$72,000, respectively. For the three months ended June 30, 2020 and 2019, amortization of patent costs totaled approximately \$14,000 and \$49,000, respectively. Approximate estimated future amortization expense is as follows:

|  |           |
|--|-----------|
| Three months ending September 30, 2020 | \$ 13,000 |
| Year ending September 30,              |           |
| 2021                                   | 51,000    |
| 2022                                   | 47,000    |
| 2023                                   | 37,000    |
| 2024                                   | 29,000    |

|            |                   |
|------------|-------------------|
| 2025       | 27,000            |
| Thereafter | 107,000           |
| Total      | <u>\$ 311,000</u> |

H. LOSS PER COMMON SHARE

In accordance with the contingently issuable shares guidance of FASB ASC Topic 260, *Earnings Per Share*, the calculation of diluted net earnings (loss) per share excludes the following securities because their inclusion would have been anti-dilutive as of June 30:

|                           | <u>2020</u>      | <u>2019</u>      |
|---------------------------|------------------|------------------|
| Options and Warrants      | 7,651,718        | 7,742,857        |
| Unvested Restricted Stock | 311,873          | 552,000          |
| Total                     | <u>7,963,591</u> | <u>8,294,857</u> |

J. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through the date these financial statements were filed and determined there are no subsequent events that require disclosure.

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**Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

Liquidity and Capital Resources

The Company's lead investigational therapy, Multikine® (Leukocyte Interleukin, Injection), is cleared for a Phase 3 clinical trial in advanced primary head and neck cancer by the regulators in twenty-four countries around the world, including the U.S.

Multikine (Leukocyte Interleukin, Injection) is the full name of this investigational therapy, which, for simplicity, is referred to in this report as Multikine. Multikine is the trademark that the Company has registered for this investigational therapy, and this proprietary name is subject to FDA review under the Company's future anticipated regulatory submission for approval. Multikine has not been licensed or approved by the FDA or any other regulatory agency. Neither has its safety or efficacy been established for any use.

The Company also owns and is developing a pre-clinical technology called LEAPS (Ligand Epitope Antigen Presentation System).

All the Company's projects are under development. Consequently, the Company cannot predict when it will be able to generate any revenue from the sale of any of its products.

Since inception, the Company has financed its operations through the sale of equity securities, convertible notes, loans and certain research grants. The Company's expenses will continue to exceed its revenues as it continues the development of Multikine and brings other drug candidates into clinical trials. Until the Company becomes profitable, any of these financing vehicles or others may be utilized to assist in funding

the Company's capital requirements.

Capital raised by the Company has been expended primarily for patent applications, research and development, administrative costs, the construction of the Company's manufacturing and laboratory facilities and the Company's Phase 3 clinical trial. The Company does not anticipate realizing significant revenues until entering into licensing arrangements for its technology and know-how or until it receives regulatory approval to sell its products (which could take several years). Thus, the Company has been dependent upon the proceeds from the sale of its securities to meet all its liquidity and capital requirements and anticipates having to do so in the future.

The Company will be required to raise additional capital or find additional long-term financing to continue with its research efforts. The ability to raise capital may be dependent upon market conditions that are outside the control of the Company. The ability of the Company to complete the necessary clinical trials and obtain FDA approval for the sale of products to be developed on a commercial basis is uncertain. Ultimately, the Company must complete the development of its products, obtain the appropriate regulatory approvals and obtain sufficient revenues to support its cost structure. There can be no assurance that the Company will be able to raise sufficient capital to support its operations.

Since the Company launched its Phase 3 clinical trial for Multikine, the Company has incurred expenses of approximately \$57.7 million as of June 30, 2020 on direct costs for the Phase 3 clinical trial. The Company estimates it will incur additional expenses of approximately \$5.3 million for the remainder of the Phase 3 clinical trial. It should be noted that this estimate is based only on the information currently available in the Company's contracts with the Clinical Research Organizations responsible for managing the Phase 3 clinical trial and does not include other related costs, e.g., the manufacturing of the drug. This number may be affected by foreign currency exchange rates, and many other factors, some of which cannot be foreseen today. It is therefore possible that the cost of the Phase 3 clinical trial will be higher than currently estimated.

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The Company uses two CRO's to manage the global Phase 3 study; ICON and Ergomed, which are both international leaders in managing oncology trials. As of September 2016, the study was fully enrolled with 928 patients.

Under a co-development agreement, Ergomed agreed to contribute up to \$12 million towards the study where it will perform clinical services in exchange for a single digit percentage of milestone and royalty payments, up to a specified maximum amount. Approximately \$10.8 million of these credits were realized as of June 30, 2020.

During the nine months ended June 30, 2020, the Company's cash increased by approximately \$11.7 million. Significant components of this increase include approximately \$14.0 million in net proceeds from the sale of common stock through public offerings, approximately \$12.1 million in proceeds from the exercise of warrants and options and employee stock purchases of approximately \$0.2 million, offset by net cash used to fund the Company's regular operations, including its Phase 3 clinical trial, of approximately \$11.7 million, approximately \$1.6 million of equipment and leasehold improvement expenditures, approximately \$0.7 million for payments of stock issuance costs and approximately \$0.6 million in lease payments. This compares with the nine months ending June 30, 2019, when the Company's cash decreased by approximately \$0.8 million. Significant components of this decrease included net cash used to fund the Company's regular operations, including its Phase 3 clinical trial, of approximately \$12.4 million and approximately \$0.3 million to purchase long term assets. The decrease was offset by net proceeds from the exercise of warrants of approximately \$11.7 million and employee stock purchases of approximately \$0.2 million.

During the nine months ended June 30, 2020, 1,544,845 warrants were exercised at a weighted average exercise price of \$7.60 for total proceeds of approximately \$11.7 million. These exercises include 849,845 warrants exercised during three months ended June 30, 2020 at a weighted average exercise price of \$11.38 for proceeds of approximately \$9.7 million. During the nine months ended June 30, 2019, 5,836,724 warrants

were exercised at a weighted average exercise price of \$2.00 for proceeds of approximately \$11.7 million. These exercises include 4,014,109 warrants exercised during the three months ended June 30, 2019 at a weighted average exercise price of \$2.08 for proceeds of approximately \$8.4 million.

The Company has entered Securities Purchase Agreements with Ergomed plc, one of the Company's Clinical Research Organizations responsible for managing the Company's Phase 3 clinical trial, to facilitate a payment of amounts due Ergomed. Under the Agreements, the Company issued Ergomed shares of common stock and the net proceeds from the sales of those shares reduces outstanding amounts due Ergomed. Upon issuance, the Company expenses the full value of the shares as Other non-operating loss and subsequently offsets the expense as amounts are realized through the sale of the Company's shares by Ergomed and reduces accounts payable to Ergomed. During the nine months ended June 30, 2020, the Company issued Ergomed 150,000 shares of common stock valued at approximately \$1.8 million. During the nine months ended June 30, 2019, the Company issued Ergomed 500,000 shares valued at approximately \$1.3 million. During the nine months ended June 30, 2020 and 2019, the Company realized approximately \$2.5 million and \$3.2 million through the sale by Ergomed of 237,479 and 808,769 shares of the Company's common stock, respectively, and the Company reduced accounts payable to Ergomed and credited Other operating gains by those amounts. For more information regarding the SPAs refer to Item 4 under Note C above.

Current assets other than cash increased by approximately \$1.2 million June 30, 2020 as compared to September 30, 2019. Receivables consist primarily of amounts due from the Company's partners for reimbursed clinical study costs related to its Phase 3 clinical trial and amounts to be reimbursed for costs related to its Small Business Innovation Research (SBIR) grant. The balance at June 30, 2020 increased \$0.2 million over the year-end balance due to the timing of costs incurred and submitted for reimbursement. Prepaid expenses at June 30, 2020 were approximately \$1.0 million higher than the balances at September 30, 2019 due to the timing of payments and recognition of related expenses, specifically an advance payment to the Company's clinical research provider.

Supplies are purchased for use in the Company's manufacturing and R&D efforts and vary with the study requirements and remained consistent period over period.



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Results of Operations and Financial Condition

During the nine months ended June 30, 2020, research and development expenses increased by approximately \$3.2 million, or 35%, compared to the nine months ended June 30, 2019. Major components of this increase include approximately \$1.9 million of costs incurred to prepare the manufacturing facility for the potential commercial manufacture of Multikine, \$1.8 million increase in employee stock compensation expense, \$0.8 million increase in depreciation expense resulting from the adoption of the new leasing standard and an increase in approximately \$0.4 million in other miscellaneous research and development expenses. These increases were offset by a decrease of approximately \$1.7 million in expenses related to the Company's on-going Phase 3 clinical trial.

During the three months ended June 30, 2020, research and development expenses increased by approximately \$1.0 million, or 32%, compared to the three months ended June 30, 2019. Major components of this increase include approximately \$0.7 million of costs incurred to prepare the manufacturing facility for the potential commercial manufacture of Multikine, \$0.8 million increase in employee stock compensation expense, \$0.3 million increase in depreciation expense resulting from adoption of the new leasing standard and an increase in approximately \$0.2 million in other miscellaneous research and development expenses. These increases were offset by a decrease of approximately \$1.0 in expenses related to the Company's on-going Phase 3 clinical trial.

During the nine months ended June 30, 2020, general and administrative expenses increased by approximately \$2.7 million, or 48%, compared to the nine months ended June 30, 2019. Approximately \$2.2 million of the change relates to an increase in employee stock compensation expense. The remaining increase consists of approximately \$0.5 million in net other general and administrative account variations.

During the three months ended June 30, 2020, general and administrative expenses increased by approximately \$0.8 million, or 36%, compared to the three months ended June 30, 2019. The difference is a result of an approximate increase of \$0.8 million in employee stock compensation expense.

The loss on derivative instruments increased by approximately \$0.3 million for the nine months ended June 30, 2020 as compared to the nine months ended June 30, 2019. The loss on derivative instruments decreased by approximately \$6.6 million for the three months ended June 30, 2020 as compared to the three months ended June 30, 2019. The variance is the result of the change in fair value of the derivative liabilities at the respective period ends. These changes were caused mainly by fluctuation in the share price of the Company's common stock.

During the three months ended June 30, 2020, the Company issued Series XX and Series YY warrants to induce holders of Series V warrants to exercise their warrants. Upon acceptance of the inducement offer, the aggregate value of the inducement warrants of approximately \$0.8 million was recorded as an expense. All unexercised Series V warrants expired.

Other non-operating gain decreased by approximately \$1.1 million for the nine months ended June 30, 2020 as compared to the nine months ended June 30, 2019. This gain relates to the SPA described in Item 4 under Note C. The amount of the gain or loss is a result of the timing of shares issued to Ergomed and the subsequent re-sale of those shares. During the nine-months ended June 30, 2020 and 2019, respectively, the Company realized approximately \$2.5 million and \$3.2 million in value upon the resale of shares. Additionally, during the nine months ended June 30, 2020 and 2019, the Company issued 150,000 and 500,000 shares to Ergomed and recorded a non-operating loss equal to the fair value of those shares of approximately \$1.8 million and \$1.3 million.

Net interest expense decreased by approximately \$0.6 million for the nine months ended June 30, 2020 compared to the nine months ended June 30, 2019 and decreased by approximately \$0.2 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019. The decrease is due to a reduction in the interest rate applied to the Company's finance leases that were re-measured in connection with the adoption of ASC 842, *Leases*, effective October 1, 2019.

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Research and Development Expenses

The Company's research and development efforts involve Multikine and LEAPS. The table below shows the research and development expenses associated with each project.

|           | <u>Nine months ended June 30,</u> |              | <u>Three months ended June 30,</u> |              |
|-----------|-----------------------------------|--------------|------------------------------------|--------------|
|           | <u>2020</u>                       | <u>2019</u>  | <u>2020</u>                        | <u>2019</u>  |
| MULTIKINE | \$ 11,174,272                     | \$ 8,524,706 | \$ 3,226,509                       | \$ 2,685,461 |
| LEAPS     | 1,337,558                         | 745,066      | 586,361                            | 280,051      |
| TOTAL     | \$ 12,511,830                     | \$ 9,269,772 | \$ 3,912,870                       | \$ 2,965,512 |

Clinical and other studies necessary to obtain regulatory approval of a new drug involve significant costs and require several years to complete. The extent of the Company's clinical trials and research programs are primarily based upon the amount of capital available to the Company and the extent to which the Company has received regulatory approvals for clinical trials. The inability of the Company to conduct clinical trials or research, whether due to a lack of capital or regulatory approval, will prevent the Company from completing the studies and research required to obtain regulatory approval for any products which the Company is developing. Without regulatory approval, the Company will be unable to sell any of its products. Since all the Company's projects are under development, the Company cannot predict when it will be able to generate any revenue from the sale of any of its products.

Critical Accounting Estimates and Policies

Management's discussion and analysis of the Company's financial condition and results of operations is based on its unaudited condensed financial statements. The preparation of these financial statements is based on the selection of accounting policies and the application of significant accounting estimates, some of which require management to make judgments, estimates and assumptions that affect the amounts reported in the financial statements and notes. The Company believes some of the more critical estimates and policies that affect its financial condition and results of operations are in the areas of operating leases and stock-based compensation. For more information regarding the Company's critical accounting estimates and policies, see Part II, Item 7 of the Company's Annual Report on Form 10-K/A for the year ended September 30, 2019. The application of these critical accounting policies and estimates has been discussed with the Audit Committee of the Company's Board of Directors.

### **Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS**

The Company does not believe that it has any significant exposures to market risk.

### **Item 4. CONTROLS AND PROCEDURES**

#### Evaluation of Disclosure Controls and Procedures

Under the direction and with the participation of the Company's management, including the Company's Chief Executive and Chief Financial Officer, the Company has conducted an evaluation of the effectiveness of the design and operation of its disclosure controls and procedures as of June 30, 2020. The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in its periodic reports with the Securities and Exchange Commission is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and regulations, and that such information is accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. The Company's disclosure controls and procedures are designed to provide a reasonable level of assurance of reaching its desired disclosure control objectives. Due to the material weakness outlined below, CEL-SCI's Chief Executive and Principal Financial and Accounting Officer has concluded that CEL-SCI's disclosure controls and procedures were not effective as of June 30, 2020.

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**Management's Report on Internal Control over Financial Reporting**

CEL-SCI's management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of CEL-SCI's Chief Executive and Principal Financial and Accounting Officer and implemented by CEL-SCI's Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of CEL-SCI's financial statements in accordance with U.S. generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Geert Kersten, CEL-SCI's Chief Executive and Principal Financial and Accounting Officer, evaluated the effectiveness of CEL-SCI's internal control over financial reporting as of June 30, 2020 based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO Framework. Management's assessment included an evaluation of the design of CEL-SCI's internal control over financial reporting and testing of the operational effectiveness of those controls.

On December 20, 2019, CEL-SCI discovered an error in the EDGAR filed Form 10-K report. The Company's complete Statements of Cash Flows for the years ended September 30, 2019 and 2018 were not included, in their entirety, in the EDGAR filed Form 10-K report filed on December 16, 2019 with the SEC. However, the entire Statements of Cash Flows were included in the Interactive Data Files ("XBRL") which were filed on December 16, 2019. The omission of the Statements of Cash Flows was the result of a failure of the Company to perform an adequate review of the EDGAR Form 10-K proof to ensure that the filing was accurate and complete. The failure of the Company to perform an adequate review of the EDGAR Form 10-K proof is a control deficiency that constitutes a material weakness.

To remediate this material weakness, the Company will change certain control activities to include the following:

The Company will compare the final EDGAR proofs with the Company reports that are provided to the EDGAR filing service to ensure that the EDGAR proofs are accurate and complete.

Based on the evaluation of CEL-SCI's internal control over financial reporting as of June 30, 2020, and the material weakness identified above, Mr. Kersten concluded that as of such date, CEL-SCI's internal control over financial reporting was not effective.

#### Changes in Internal Control over Financial Reporting

Other than the improvement noted in the preceding section, there were no other changes in the Company's internal control over financial reporting that occurred during the quarter ended June 30, 2020 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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## **PART II**

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

During the nine months ended June 30, 2020 the Company issued 47,750 restricted shares of common stock to consultants for investor relations services.

The Company relied upon the exemption provided by Section 4(a)(2) of the Securities Act of 1933 with respect to the issuance of these shares. The individuals who acquired these shares were sophisticated investors and were provided full information regarding the Company's business and operations. There was no general solicitation in connection with the offer or sale of these securities. The individuals who acquired these shares acquired them for their own accounts. The certificates representing these shares bear a restricted legend which provides they cannot be sold

except pursuant to an effective registration statement or an exemption from registration. No commission or other form of remuneration was given to any person in connection with the issuance of these shares.

**Item 6. Exhibits**

| <b>Number</b>      | <b>Exhibit</b>                                |
|--------------------|---|
| <a href="#">31</a> | <a href="#">Rule 13a-14(a) Certifications</a> |
| <a href="#">32</a> | <a href="#">Section 1350 Certifications</a>   |



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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.

CEL-SCI CORPORATION

Date: August 10, 2020

By: /s/ Geert Kersten  
Geert Kersten  
Principal Executive Officer\*

**CERTIFICATIONS**

I, Geert Kersten, certify that:

1. I have reviewed this quarterly report on Form 10-Q/A of CEL-SCI Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, considering the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or cause such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of the internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have significant role in the registrant's internal control over financial reporting.

August 10, 2020

By: /s/ Geert Kersten  
Geert Kersten  
Principal Executive Officer

**CERTIFICATIONS**

I, Geert Kersten, certify that:

1. I have reviewed this quarterly report on Form 10-Q/A of CEL-SCI Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, considering the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects

the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

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

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

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

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

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

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

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

August 10, 2020

By: /s/ Geert Kersten  
Geert Kersten  
Principal Financial Officer

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In connection with the Quarterly Report of CEL-SCI Corporation (the "Company") on Form 10-Q/A for the period ending June 30, 2020 as filed with the Securities and Exchange Commission (the "Report"), Geert Kersten, the Principal Executive and Financial Officer of the Company, certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of the Company.

By: /s/ Geert Kersten  
Geert Kersten  
Principal Executive and  
Principal Financial Officer

August 10, 2020