

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

Form 10-Q

(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, 2021

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: 000-29959

Cassava Sciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

91-1911336  
(I.R.S. Employer  
Identification Number)

7801 N. Capital of Texas Highway, Suite 260, Austin, TX 78731  
(512) 501-2444  
(Address, including zip code, of registrant's principal executive offices and  
telephone number, including area code)

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

| Title of each class             | Trading<br>Symbol(s) | Name of each exchange on which registered |
|---------------------------------|----------------------|---|
| Common Stock, \$0.001 par value | SAVA                 | NASDAQ Capital Market                     |

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

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

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

Large Accelerated Filer   
Non-accelerated Filer

Accelerated Filer   
Smaller Reporting Company   
Emerging Growth Company

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

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

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

Common Stock, \$0.001 par value

40,014,695  
Shares Outstanding as of August 2, 2021

CASSAVA SCIENCES, INC.

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## PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

**CASSAVA SCIENCES, INC.**  
**CONDENSED BALANCE SHEETS**  
(Unaudited, in thousands, except share and par value data)

|  | <u>June 30, 2021</u> | <u>December 31,<br/>2020</u> |
|--|----------------------|------------------------------|
| <b>ASSETS</b>  |                      |                              |
| Current assets:  |                      |                              |
| Cash and cash equivalents  | \$ 278,254           | \$ 93,506                    |
| Prepaid expenses and other current assets  | 1,304                | 488                          |
| Total current assets   | 279,558              | 93,994                       |
| Operating lease right-of-use assets  | 252                  | 295                          |
| Property and equipment, net  | 75                   | 11                           |
| Other assets   | 1,420                | —                            |
| Total assets   | <u>\$ 281,305</u>    | <u>\$ 94,300</u>             |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                      |                              |
| Current liabilities:   |                      |                              |
| Accounts payable   | \$ 1,912             | \$ 911                       |
| Accrued development expense  | 2,462                | 719                          |
| Accrued compensation and benefits  | 120                  | 83                           |
| Operating lease liabilities, current   | 93                   | 58                           |
| Other current liabilities  | 50                   | 94                           |
| Total current liabilities  | 4,637                | 1,865                        |
| Operating lease liabilities, non-current   | 188                  | 235                          |
| Total liabilities  | 4,825                | 2,100                        |
| Commitments and contingencies (Notes 6 and 8)  |                      |                              |
| Stockholders' equity:  |                      |                              |
| Preferred stock, \$0.001 par value; 10,000,000 shares authorized, none issued and outstanding  | —                    | —                            |
| Common stock, \$0.001 par value; 120,000,000 shares authorized; 40,011,894 and 35,237,987 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively | 40                   | 35                           |
| Additional paid-in capital   | 460,012              | 267,086                      |
| Accumulated deficit  | (183,572)            | (174,921)                    |
| Total stockholders' equity   | 276,480              | 92,200                       |
| Total liabilities and stockholders' equity   | <u>\$ 281,305</u>    | <u>\$ 94,300</u>             |

See accompanying notes to condensed financial statements.

**CASSAVA SCIENCES, INC.**

**CONDENSED STATEMENTS OF OPERATIONS**  
(Unaudited, in thousands, except per share data)

|  | Three months ended |                   | Six months ended  |                   |
|--|--------------------|-------------------|-------------------|-------------------|
|  | June 30,           |                   | June 30,          |                   |
|  | 2021               | 2020              | 2021              | 2020              |
| Operating expenses:  |                    |                   |                   |                   |
| Research and development, net of grant reimbursement           | \$ 3,901           | \$ 591            | \$ 6,430          | \$ 1,135          |
| General and administrative                                     | 1,237              | 818               | 2,241             | 1,596             |
| Gain on sale of property and equipment                         | —                  | (246)             | —                 | (346)             |
| Total operating expenses                                       | <u>5,138</u>       | <u>1,163</u>      | <u>8,671</u>      | <u>2,385</u>      |
| Operating loss   | (5,138)            | (1,163)           | (8,671)           | (2,385)           |
| Interest income  | 13                 | 27                | 20                | 99                |
| Net loss   | <u>\$ (5,125)</u>  | <u>\$ (1,136)</u> | <u>\$ (8,651)</u> | <u>\$ (2,286)</u> |
| Net loss per share, basic and diluted                          | <u>\$ (0.13)</u>   | <u>\$ (0.05)</u>  | <u>\$ (0.22)</u>  | <u>\$ (0.09)</u>  |
| Shares used in computing net loss per share, basic and diluted | <u>39,953</u>      | <u>24,779</u>     | <u>38,843</u>     | <u>24,630</u>     |

See accompanying notes to condensed financial statements.

**CASSAVA SCIENCES, INC.**

**CONDENSED STATEMENTS OF CASH FLOWS**

(Unaudited, in thousands)

|   | Six months ended June 30, |            |
|---|---------------------------|------------|
|   | 2021                      | 2020       |
| <b>Cash flows from operating activities:</b>                                |                           |            |
| Net loss  | \$ (8,651)                | \$ (2,286) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                           |            |
| Stock-based compensation  | 665                       | 522        |
| Depreciation and amortization   | 9                         | 20         |
| Gain on sale of property and equipment                                      | —                         | (346)      |
| Changes in operating assets and liabilities:                                |                           |            |
| Prepaid and other assets  | (2,236)                   | 82         |
| Operating lease right-of-use assets and liabilities                         | 31                        | —          |
| Accounts payable  | 1,001                     | (37)       |
| Accrued development expense   | 1,743                     | (22)       |
| Accrued compensation and benefits   | 37                        | 26         |
| Other current liabilities   | (44)                      | 5          |
| Net cash used in operating activities                                       | (7,445)                   | (2,036)    |
| <b>Cash flows from investing activities:</b>                                |                           |            |
| Purchase of property and equipment  | (73)                      | —          |
| Proceeds from sale of property and equipment                                | —                         | 360        |
| Net cash (used in) provided by investing activities                         | (73)                      | 360        |
| <b>Cash flows from financing activities:</b>                                |                           |            |
| Proceeds from exercise of stock options                                     | 1,749                     | —          |
| Proceeds from exercise of common stock warrants                             | 692                       | 3,849      |
| Proceeds from registered direct offering, net of issuance costs             | 189,825                   | —          |
| Net cash provided by financing activities                                   | 192,266                   | 3,849      |
| Net increase in cash and cash equivalents                                   | 184,748                   | 2,173      |
| Cash and cash equivalents at beginning of period                            | 93,506                    | 23,081     |
| Cash and cash equivalents at end of period                                  | \$ 278,254                | \$ 25,254  |

See accompanying notes to condensed financial statements.

Notes to Condensed Financial Statements  
(Unaudited)**Note 1. General and Liquidity**

Cassava Sciences, Inc. (the “Company”) discovers and develops proprietary pharmaceutical product candidates that may offer significant improvements to patients and healthcare professionals. The Company generally focuses its discovery and product development efforts on disorders of the nervous system.

The accompanying unaudited condensed financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial information and pursuant to the instructions to the Quarterly Report on Form 10-Q and Article 10 of Regulation S-X. Accordingly, the condensed financial statements do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management of the Company, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2021 are not necessarily indicative of the results that may be expected for any other interim period or for the year 2021. For further information, refer to the financial statements and footnotes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2020.

***Coronavirus Disease 2019 (COVID-19)***

The widespread outbreak of a novel infectious disease called Coronavirus Disease 2019, or COVID-19, has not significantly impacted the Company’s operations or financial condition as of August 4, 2021. However, this pandemic has created a dynamic and uncertain situation in the national economy. The Company continues to closely monitor the latest information to make timely, informed business decisions and public disclosures regarding the potential impact of pandemic on its operations and financial condition. The scope of pandemic is unprecedented and its long-term impact on the Company’s operations and financial condition cannot be reasonably estimated at this time.

***Liquidity***

The Company has incurred significant net losses and negative cash flows since inception, and as a result has an accumulated deficit of \$183.6 million at June 30, 2021. The Company expects its cash requirements to be significant in the future. The amount and timing of the Company’s future cash requirements will depend on regulatory and market acceptance of its product candidates and the resources it devotes to researching and developing, formulating, manufacturing, commercializing and supporting its products. The Company may seek additional funding through public or private financing in the future, if such funding is available and on terms acceptable to the Company. There are no assurances that additional financing will be available on favorable terms, or at all. However, management believes that the current working capital position will be sufficient to meet the Company’s working capital needs for at least the next 12 months.

**Note 2. Significant Accounting Policies*****Use of Estimates***

The Company makes estimates and assumptions in preparing its condensed financial statements in conformity with GAAP. These estimates and assumptions affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed financial statements and the reported amount of revenue earned and expenses incurred during the reporting period. The Company evaluates its estimates on an ongoing basis, including those estimates related to manufacturing agreements and research collaborations. Actual results could differ from these estimates and assumptions.

***Cash and Cash Equivalents and Concentration of Credit Risk***

The Company invests in cash and cash equivalents. The Company considers highly liquid financial instruments with original maturities of three months or less to be cash equivalents. Highly liquid investments that are considered

cash equivalents include money market accounts and funds, certificates of deposits, and U.S. Treasury securities. The Company maintains its cash and cash equivalents at one financial institution.

### ***Fair Value Measurements***

The Company recognizes financial instruments in accordance with the authoritative guidance on fair value measurements and disclosures for financial assets and liabilities. This guidance defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements. The guidance also establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

- Level 1 includes quoted prices in active markets.
- Level 2 includes significant observable inputs, such as quoted prices for identical or similar securities, or other inputs that are observable and can be corroborated by observable market data for similar securities. The Company uses market pricing and other observable market inputs obtained from third-party providers. It uses the bid price to establish fair value where a bid price is available. The Company does not have any financial instruments where the fair value is based on Level 2 inputs.
- Level 3 includes unobservable inputs that are supported by little or no market activity. The Company does not have any financial instruments where the fair value is based on Level 3 inputs.

If a financial instrument uses inputs that fall in different levels of the hierarchy, the instrument will be categorized based upon the lowest level of input that is significant to the fair value calculation. The fair value of cash and cash equivalents was based on Level 1 inputs at June 30, 2021 and December 31, 2020.

### ***Proceeds from Grants***

During the three months ended June 30, 2021 and 2020, the Company received reimbursements totaling \$0.9 million and \$1.1 million pursuant to National Institutes of Health (“NIH”) research grants, respectively. During the six months ended June 30, 2021 and 2020, the Company received reimbursements totaling \$1.5 million and \$2.4 million pursuant to NIH research grants, respectively. The Company records the proceeds from these grants as reductions to its research and development expenses.

### ***Stock-based Compensation***

The Company recognizes non-cash expense for the fair value of all stock options and other share-based awards. The Company uses the Black-Scholes option valuation model (“Black-Scholes”) to calculate the fair value of stock options, using the single-option award approach and straight-line attribution method. For all options granted, it recognizes the resulting fair value as expense on a straight-line basis over the vesting period of each respective stock option, generally four years.

The Company has granted share-based awards that vest upon achievement of certain performance criteria (“Performance Awards”). The Company multiplies the number of Performance Awards by the fair value of its common stock on the date of grant to calculate the fair value of each award. It estimates an implicit service period for achieving performance criteria for each award. The Company recognizes the resulting fair value as expense over the implicit service period when it concludes that achieving the performance criteria is probable. It periodically reviews and updates as appropriate its estimates of implicit service periods and conclusions on achieving the performance criteria. Performance Awards vest and common stock is issued upon achievement of the performance criteria.

### ***Net Loss per Share***

The Company computes basic net loss per share on the basis of the weighted-average number of common shares outstanding for the reporting period. Diluted net loss per share is computed on the basis of the weighted-average number of common shares outstanding plus potential dilutive common shares outstanding using the treasury-stock method. Potential dilutive common shares consist of outstanding common stock options and warrants. There is no difference between the Company’s net loss and comprehensive loss.

The Company included the following in the calculation of basic and diluted net loss per share (in thousands, except per share data):

|   | Three months ended |                  | Six months ended |                  |
|---|--------------------|------------------|------------------|------------------|
|   | June 30,           |                  | June 30,         |                  |
|   | 2021               | 2020             | 2021             | 2020             |
| <b>Numerator:</b>   |                    |                  |                  |                  |
| Net loss  | \$ (5,125)         | \$ (1,136)       | \$ (8,651)       | \$ (2,286)       |
| <b>Denominator:</b>   |                    |                  |                  |                  |
| Shares used in computing net loss per share, basic and diluted          | 39,953             | 24,779           | 38,843           | 24,630           |
| Net loss per share, basic and diluted                                   | <u>\$ (0.13)</u>   | <u>\$ (0.05)</u> | <u>\$ (0.22)</u> | <u>\$ (0.09)</u> |
| Dilutive common stock options excluded from net loss per share, diluted | 2,129              | 2,294            | 2,163            | 2,177            |
| Common stock warrants excluded from net loss per share, diluted         | —                  | 1,427            | —                | 1,427            |

The Company excluded common stock options and warrants outstanding from the calculation of net loss per share, diluted, because the effect of including options and warrants outstanding would have been anti-dilutive.

#### **Fair Value of Financial Instruments**

Financial instruments include accounts payable and accrued liabilities. The estimated fair value of certain financial instruments may be determined using available market information or other appropriate valuation methodologies. However, considerable judgment is required in interpreting market data to develop estimates of fair value; therefore, the estimates are not necessarily indicative of the amounts that could be realized or would be paid in a current market exchange. The effect of using different market assumptions and/or estimation methodologies may be material to the estimated fair value amounts. The carrying amounts of accounts payable and accrued liabilities are at cost, which approximates fair value due to the short maturity of those instruments.

#### **Research Contract Costs and Accruals**

The Company has entered into various research and development contracts with research institutions and other third-party vendors. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from actual costs.

#### **Incentive Bonus Plan**

In 2020, the Company established the 2020 Cash Incentive Bonus Plan (the "Plan") to incentivize Plan participants. Awards under the Plan are accounted for as liability awards under Accounting Standards Codification (ASC) 718 "Stock-based Compensation". The fair value of each potential Plan award will be determined once a grant date occurs and will be remeasured each reporting period. Compensation expense associated with the Plan will be recognized over the expected achievement period for each Plan award, when a Performance Condition is considered probable of being met. See Note 8 for further discussion of the Plan.

#### **Leases**

The Company recognizes assets and liabilities that arise from leases. For operating leases, the Company is required to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments during the lease term, in the condensed balance sheets. The Company elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company does not recognize right-of-use assets or lease liabilities. As the Company's leases do not provide an implicit rate, it uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. Lease expense for lease payments is recognized on a straight-line basis over the lease term.



## Income Taxes

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax balances are adjusted to reflect tax rates based on currently enacted tax laws, which will be in effect in the years in which the temporary differences are expected to reverse. The Company has accumulated significant deferred tax assets that reflect the tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of certain deferred tax assets is dependent upon future earnings. The Company is uncertain about the timing and amount of any future earnings. Accordingly, the Company offsets these deferred tax assets with a valuation allowance.

The Company accounts for uncertain tax positions in accordance with ASC 740, "Income Taxes", which clarifies the accounting for uncertainty in tax positions. These provisions require recognition of the impact of a tax position in the Company's condensed financial statements only if that position is more likely than not of being sustained upon examination by taxing authorities, based on the technical merits of the position. Any interest and penalties related to uncertain tax positions will be reflected as a component of income tax expense.

### Note 3. Prepaid and Other Assets

Prepaid and other assets at June 30, 2021 and December 31, 2020 consisted of the following (in thousands):

|   | June 30, 2021   | December 31, 2020 |
|---|-----------------|-------------------|
| Prepaid insurance                               | \$ —            | \$ 457            |
| Contract research organization deposit          | 1,166           | —                 |
| Other   | 138             | 31                |
| Total prepaid expenses and other current assets | <u>\$ 1,304</u> | <u>\$ 488</u>     |
| Contract research organization deposit          | \$ 1,420        | \$ —              |
| Total other assets                              | <u>\$ 1,420</u> | <u>\$ —</u>       |

### Note 4. Stockholders' Equity and Stock-Based Compensation Expense

Stockholders' Equity Activity during the Six Months Ended June 30, 2021 and 2020

During the six months ended June 30, 2021 and 2020, the Company's common stock outstanding and stockholders' equity changed as follows:

|   | Common Stock      | Stockholders' equity<br>(in thousands) |
|---|-------------------|--|
| Balance at December 31, 2019                    | 21,841,810        | \$ 22,099                              |
| Stock-based compensation for:                   |                   |  |
| Stock options for employees                     | —                 | 261                                    |
| Stock options for non-employees                 | —                 | 9                                      |
| Proceeds from exercise of common stock warrants | 2,888,092         | 3,613                                  |
| Net loss  | —                 | (1,150)                                |
| Balance at March 31, 2020                       | <u>24,729,902</u> | <u>\$ 24,832</u>                       |
| Stock-based compensation for:                   |                   |  |
| Stock options for employees                     | —                 | 249                                    |
| Stock options for non-employees                 | —                 | 3                                      |
| Proceeds from exercise of common stock warrants | 189,431           | 236                                    |
| Net loss  | —                 | (1,136)                                |
| Balance at June 30, 2020                        | <u>24,919,333</u> | <u>\$ 24,184</u>                       |

|  |                   |           |                |
|--|-------------------|-----------|----------------|
| Balance at December 31, 2020                             | 35,237,987        | \$        | 92,200         |
| Stock-based compensation for:                            |                   |           |                |
| Stock options for employees                              | —                 |           | 249            |
| Stock options for non-employees                          | —                 |           | 1              |
| Proceeds from exercise of common stock warrants          | 554,019           |           | 692            |
| Exercise of stock options                                | 135,015           |           | 1,746          |
| Proceeds from registered direct offering of common stock | 4,081,633         |           | 189,825        |
| Net loss   | —                 |           | (3,526)        |
| Balance at March 31, 2021                                | <u>40,008,654</u> | <u>\$</u> | <u>281,187</u> |
| Stock-based compensation for:                            |                   |           |                |
| Stock options for employees                              | —                 |           | 410            |
| Stock options for non-employees                          | —                 |           | 5              |
| Exercise of stock options                                | 3,240             |           | 3              |
| Net loss   | —                 |           | (5,125)        |
| Balance at June 30, 2021                                 | <u>40,011,894</u> | <u>\$</u> | <u>276,480</u> |

#### *2021 Registered Direct Offering*

On February 12, 2021, the Company completed a common stock offering pursuant to which certain investors purchased 4,081,633 shares of common stock at a price of \$49.00 per share. Net proceeds of the offering were approximately \$189.8 million after deducting offering expenses.

#### *At-the-Market Common Stock Offering*

In March 2020, the Company established an at-the-market offering program (“ATM”) to sell, from time to time, shares of Company common stock having an aggregate offering price of up to \$100 million in transactions pursuant to a shelf registration statement that was declared effective by the U.S. Securities and Exchange Commission (the “SEC”) on May 5, 2020. The Company is obligated to pay a commission of 3.0% of the gross proceeds from the sale of shares of common stock in the offering. The Company is not obligated to sell any shares in the offering.

There were no common stock sales under the ATM during the three and six months ended June 30, 2021 and 2020.

#### *Common Stock Warrants*

In August 2018, the Company issued warrants to purchase up to an aggregate of 9.1 million shares of its common stock in conjunction with an offering of its common stock.

The Company did not receive any proceeds from exercise of common stock warrants during the three months ended June 30, 2021. During the three months ended June 30, 2020, the Company received proceeds of \$0.2 million from the exercise of 0.2 million shares pursuant to warrants.

During the six months ended June 30, 2021, the Company received proceeds of \$0.7 million from the exercise of 0.6 million shares pursuant to warrants. During the six months ended June 30, 2020, the Company received proceeds of \$3.8 million from the exercise of 3.1 million shares pursuant to warrants.

There were no remaining common stock warrants outstanding as of June 30, 2021.

#### *Stock Option and Performance Award Activity in 2021*

During the six months ended June 30, 2021, stock options and unvested Performance Awards outstanding under the Company’s stock option plans changed as follows:

|                                     | <u>Stock Options</u> | <u>Performance Awards</u> |
|-------------------------------------|----------------------|---------------------------|
| Outstanding as of December 31, 2020 | 2,817,504            | 138,055                   |
| Options granted                     | 85,000               | —                         |
| Options exercised                   | (234,994)            | —                         |
| Options forfeited/canceled          | (9,338)              | —                         |
| Outstanding as of June 30, 2021     | <u>2,658,172</u>     | <u>138,055</u>            |

The weighted average exercise price of options outstanding at June 30, 2021 was \$11.40. As outstanding options vest over the current remaining vesting period of 2.2 years, the Company expects to recognize stock-based compensation expense of \$6.7 million. If and when outstanding Performance Awards vest, the Company will recognize stock-based compensation expense of \$2.3 million over the implicit service period.

During the three months ended June 30, 2021, there were 71,596 stock options exercised. Of the stock options exercised, 68,356 stock options were net settled in satisfaction of the exercise price, with no cash proceeds received. Cash proceeds to the Company totaled \$3,000 during the three months ended June 30, 2021.

During the six months ended June 30, 2021, there were 234,994 stock options exercised. Of the stock options exercised, 98,739 stock options were net settled in satisfaction of the exercise price, with no cash proceeds received. Cash proceeds to the Company totaled \$1,749,000 during the six months ended June 30, 2021.

There were no stock options exercised during the three and six months ended June 30, 2020.

Subsequent to June 30, 2021, there were 2,801 stock options exercised for cash proceeds of \$57,000.

#### *Stock-based Compensation Expense in 2021*

During the three and six months ended June 30, 2021 and 2020, the Company's stock-based compensation expense was as follows (in thousands):

|  | <u>Three months ended</u> |               | <u>Six months ended</u> |               |
|--|---------------------------|---------------|-------------------------|---------------|
|  | <u>June 30,</u>           |               | <u>June 30,</u>         |               |
|  | <u>2021</u>               | <u>2020</u>   | <u>2021</u>             | <u>2020</u>   |
| Research and development               | \$ 295                    | \$ 111        | \$ 415                  | \$ 226        |
| General and administrative             | 120                       | 141           | 250                     | 296           |
| Total stock-based compensation expense | <u>\$ 415</u>             | <u>\$ 252</u> | <u>\$ 665</u>           | <u>\$ 522</u> |

#### *2018 Equity Incentive Plan*

In January 2018, the Company's Board of Directors (the "Board") approved the Company's 2018 Omnibus Incentive Plan (the "2018 Plan"). The Board or a designated committee of the Board is responsible for administration of the 2018 Plan and determines the terms and conditions of each option granted, consistent with the terms of the 2018 Plan. The Company's employees, directors, and consultants are eligible to receive awards under the 2018 Plan, including grants of stock options and Performance Awards. Share-based awards generally expire 10 years from the date of grant. The 2018 Plan provides for issuance of up to 1,000,000 shares of common stock, par value \$0.001 per share, subject to adjustment as provided in the 2018 Plan.

When stock options or Performance Awards are exercised net of the exercise price and taxes, the number of shares of stock issued is reduced by the number of shares equal to the amount of taxes owed by the award recipient and that number of shares are cancelled. The Company then uses its cash to pay tax authorities the amount of statutory taxes owed by and on behalf of the award recipient.

**Note 5. Income Taxes**

The Company did not provide for income taxes during the three and six months ended June 30, 2021, because it has projected a net loss for the full year 2021 for which any benefit will be offset by an increase in the valuation allowance. There was also no provision for income taxes for the three and six months ended June 30, 2020.

**Note 6. Commitments***Right-of-use Asset and Liability*

The Company has a non-cancelable operating lease for approximately 6,000 square feet of office space in Austin, Texas that expires on April 30, 2024. The Company also has a short-term lease agreement for an additional 3,600 square feet of office space in Austin, Texas that expires on April 30, 2022. Future lease payments as of June 30, 2021 are as follows (in thousands):

| <b>Future lease payments</b> |    | <b>2021</b> | <b>2022</b> | <b>2023</b> | <b>2024</b> | Total future lease payments | Less: imputed interest |    | Total |
|------------------------------|----|-------------|-------------|-------------|-------------|-----------------------------|------------------------|----|-------|
| Operating leases             | \$ | 50          | 102         | 107         | 36          | 295                         | (14)                   | \$ | 281   |
| Short-term operating lease   | \$ | 32          | 21          | —           | —           | 53                          | —                      | \$ | 53    |

Rent expense for the three months ended June 30, 2021 and 2020 totaled \$34,000 and \$25,000, respectively.

Rent expense for the six months ended June 30, 2021 and 2020 totaled \$57,000 and \$50,000, respectively.

Cash paid for operating lease liabilities during the three months ended June 30, 2021 and 2020 totaled \$27,000 and \$25,000, respectively. Cash paid for operating lease liabilities during the six months ended June 30, 2021 and 2020 totaled \$27,000 and \$50,000, respectively.

*Other Commitments*

The Company conducts its product research and development programs through a combination of internal and collaborative programs that include, among others, arrangements with universities, contract research organizations and clinical research sites. The Company has contractual arrangements with these organizations that are cancelable. The Company's obligations under these contracts are largely based on services performed. The Company also had non-cancellable commitments for the manufacture of simufilam totaling approximately \$1.9 million at June 30, 2021.

**Note 7. Sale of Property and Equipment**

There were no sales of property and equipment during the three and six months ended June 30, 2021.

During the three months ended June 30, 2020, the Company sold surplus manufacturing equipment to a third party and received proceeds totaling \$260,000. During the six months ended June 30, 2020, the Company sold surplus manufacturing equipment to a third party and received proceeds totaling \$360,000. The original cost of the property and equipment was \$892,000 and accumulated depreciation was \$878,000, resulting a gain on sale of property and equipment of \$246,000 and \$346,000, respectively, during the three and six months ended June 30, 2020.

**Note 8. 2020 Cash Incentive Bonus Plan**

On August 26, 2020, the Board approved the Plan. The Plan was established to promote the long-term success of the Company by creating an "at-risk" cash bonus program that rewards Plan participants with additional cash compensation in lockstep with significant increases in the Company's market capitalization. The Plan is considered "at-risk" because Plan participants will not receive a cash bonus unless the Company's market capitalization increases significantly and certain other conditions specified in the Plan are met. Specifically, Plan participants will not be paid any cash bonuses unless (1) the Company completes a merger or acquisition transaction that constitutes a sale of ownership of the Company or its assets (a Merger Transaction) or (2) the Compensation Committee of the Board (the Compensation Committee) determines the Company has sufficient cash on hand, as defined in the Plan. Because of the inherent discretion and uncertainty regarding these requirements, the Company has concluded that a Plan grant date has not occurred as of June 30, 2021.

Plan participants will be paid all earned cash bonuses in the event of a Merger Transaction.

The Company's market capitalization for purposes of the Plan is determined based on either (1) the Company's closing price of one share on the Nasdaq Capital Market multiplied by the total issued and outstanding shares and options to purchase shares of the Company, or (2) the aggregate consideration payable to security holders of the Company in a Merger Transaction. This constitutes a market condition under applicable accounting guidance.

The Plan triggers a potential cash bonus each time the Company's market capitalization increases significantly, up to a maximum \$5 billion in market capitalization. The Plan specifies 14 incremental amounts between \$200 million and \$5 billion (each increment, a "Valuation Milestone"). Each Valuation Milestone triggers a potential cash bonus award in a pre-set amount defined in the Plan. Each Valuation Milestone must be achieved and maintained for no less than 20 consecutive trading days for Plan participants to be eligible for a potential cash bonus award. Approximately 58% of each cash bonus award associated with a Valuation Milestone is subject to adjustment and approval by the Compensation Committee. Any amounts not awarded by the Compensation Committee are no longer available for distribution.

If the Company were to exceed a \$5 billion market capitalization for no less than 20 consecutive trading days, all Valuation Milestones would be deemed achieved, in which case cash bonus awards would range from a minimum of \$139.1 million up to a hypothetical maximum of \$322.3 million. Payment of cash bonuses is deferred until such time as (1) the Company completes a Merger Transaction, or (2) the Compensation Committee determines the Company has sufficient cash on hand to render payment (each, a "Performance Condition"), neither of which may ever occur. Accordingly, there can be no assurance that Plan participants will ever be paid a cash bonus that is awarded under the Plan, even if the Company's market capitalization increases significantly.

The Plan is accounted for as a liability award. The fair value of each Valuation Milestone award will be determined once a grant date occurs and will be remeasured each reporting period. Compensation expense associated with the Plan will be recognized over the expected achievement period for each of the 14 Valuation Milestones, when a Performance Condition is considered probable of being met.

On October 13, 2020, the Company achieved the first Valuation Milestone. Subsequently, the Compensation Committee approved a potential cash bonus award of \$7.3 million in total for all Plan participants, subject to future satisfaction of a Performance Condition.

During the six months ended June 30, 2021, the Company achieved 10 Valuation Milestones triggering potential Company obligations to all Plan participants from a minimum of \$81.0 million up to a hypothetical maximum of \$195.0 million, to be determined by the Compensation Committee. However, no compensation expense has been recorded since no grant date has occurred and no Performance Conditions are considered probable of being met. There is no continuing service requirement for Plan participants once the Compensation Committee approves a cash bonus award.

Subsequent to June 30, 2021, the Company achieved one additional Valuation Milestone triggering potential Company obligations to all Plan participants from a minimum of \$12.7 million up to a hypothetical maximum of \$30.0 million, to be determined by the Compensation Committee and contingent upon future satisfaction of a Performance Condition.

No actual cash payments were authorized or made to participants under the Plan through June 30, 2021.

#### **Note 9. Recently Issued Accounting Pronouncements**

In December 2019, the FASB issued Accounting Standards Update ("ASU") No. 2019-12, *Income Taxes (Topic 740) Simplifying Accounting for Income Taxes*, as part of its initiative to reduce complexity in the accounting standards. The guidance amended certain disclosure requirements that had become redundant, outdated or superseded. Additionally, this guidance amends accounting for the interim period effects of changes in tax laws or rates, and simplifies aspects of the accounting for franchise taxes. The guidance is effective for annual periods beginning after December 15, 2020, including interim periods therein. The adoption of ASU 2019-12 in the first quarter of 2021 did not have a material impact on the Company's condensed financial statements.

## Note 10. Subsequent Event

On August 4, 2021, the Company completed the purchase of a two-building office complex in Austin, Texas, which will serve as its new corporate headquarters. This property is intended to accommodate the Company's anticipated significant growth and expansion of its operations in the coming years. Company management expects to be hands-off with regards to property management. Maintenance, physical facilities, leasing, property management and other key responsibilities around property ownership will all be assumed by professional real-estate managers under long-term contract with the Company. The property purchase price was \$21.9 million, exclusive of closing costs, funded with cash on hand. The office complex measures approximately 90,000 rentable square feet. The property is currently 59% leased, before the effect of the Company occupying approximately 25% of the property in the near future. The seller is an independent third party not affiliated with the Company.

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

This discussion and analysis should be read in conjunction with Cassava Sciences, Inc.'s (the "Company," "we," "us," or "our") condensed financial statements and accompanying notes included elsewhere in this Quarterly Report on Form 10-Q. Operating results are not necessarily indicative of results that may occur in future periods.

This Quarterly Report on Form 10-Q contains certain statements that are considered forward-looking statements within the meaning of the Private Securities Reform Act of 1995. We intend that such statements be protected by the safe harbor created thereby. Forward-looking statements relate to expectations, beliefs, projections, future plans and strategies, anticipated events or trends and similar expressions concerning matters that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "should," "will" and "would" or the negatives of these terms or other comparable terminology.

The forward-looking statements are based on our beliefs, assumptions and expectations of our future performance, taking into account all information currently available to us. Forward-looking statements involve risks and uncertainties and our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Examples of such forward-looking statements include, but are not limited to statements about:

- our intention to initiate a pivotal Phase 3 clinical program with simufilam in Alzheimer's disease, the anticipated scope of Phase 3 studies and our estimated timeline for doing so;
- our reliance on third-party contractors to make drug supply on a large-scale for our Phase 3 clinical program, or their ability to do so on-time or on-budget;
- limitations around the interpretation of cognitive results from a long-term open-label study design, as compared to efficacy results from a fully completed, randomized controlled study design;
- the expected rate of cognitive decline over time in untreated Alzheimer's patients;
- the ability of the Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-cog), Alzheimer's Disease Cooperative Study – Activities of Daily Living (ADCS-ADL), Neuropsychiatric Inventory (NPI), CANTAB or other clinical scales to assess cognition or health in our trials of Alzheimer's disease;
- announcements or plans regarding any future interim analyses of our open-label study of simufilam and our estimated timeline for doing so;
- any significant changes we have made, or anticipate making, to the design of an on-going open-label study of simufilam;
- announcements regarding an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA);
- our ability to initiate, conduct or analyze additional clinical and non-clinical studies with our product candidates targeted at Alzheimer's disease and other neurodegenerative diseases;
- the interpretation of results from our Phase 2 clinical studies;
- our estimated timeline for publishing in a peer-reviewed technical journal clinical results of our Phase 2b study of simufilam;
- our plans to further develop SavaDx, our investigational blood-based diagnostic, and our estimated timeline for doing so;
- the safety, efficacy, or potential therapeutic benefits of our product candidates;

- the utility of protection, or the sufficiency, of our intellectual property;
- our potential competitors or competitive products;
- expected future sources of revenue and capital and increasing cash needs;
- our use of Clinical Research Organizations (CROs) to conduct clinical studies of our product candidates;
- expectations regarding trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions;
- our expenses increasing or fluctuations in our financial or operating results;
- our operating losses and anticipated operating and capital expenditures;
- expectations regarding the issuance of shares of common stock to employees pursuant to equity compensation awards, net of employment taxes;
- the development and maintenance of our internal information systems and infrastructure;
- our need to hire additional personnel and our ability to attract and retain such personnel;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our need to expand the size and scope of our physical facilities;
- the sufficiency of our current resources to continue to fund our operations;
- the accuracy of our estimates regarding expenses, capital requirements, and needs for additional financing;
- assumptions and estimates used for our disclosures regarding stock-based compensation; and
- the long-term impact of COVID-19, a novel coronavirus first detected in 2019, on our operations and financial condition.

Such forward-looking statements and our business involve risks and uncertainties, including, but not limited to the following:

- We are in the early stages of clinical drug development and have a limited operating history in our business targeting Alzheimer's disease and no products approved for commercial sale.
- We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses for the foreseeable future.
- Research and development of biopharmaceutical products is a highly uncertain undertaking and involves a substantial degree of risk and our business is heavily dependent on the successful development of our product candidates.
- We may need to obtain substantial additional financing to complete the development and any commercialization of our product candidates.
- We may not be successful in our efforts to continue to develop product candidates or commercially successful products.
- We may not be successful in our efforts to expand indications for product candidates.
- We are concentrating a substantial portion of our research and development efforts on the diagnosis and treatment of Alzheimer's disease, an area of research that has recorded many clinical failures.
- We may encounter substantial delays in our clinical trials or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.
- Our clinical trials may fail to demonstrate evidence of the safety and efficacy of our product candidates, which would prevent, delay, or limit the scope of regulatory approval and the commercialization of our product candidates.
- We may be unable to protect our intellectual property rights or trade secrets.
- We may be subject to third-party claims of intellectual property infringement.
- We may not succeed in our maintenance or pursuit of licensing rights or third-party intellectual property necessary for the development of our product candidates.
- Enacted or future legislation or regulatory actions may adversely affect our product pricing, or limit the reimbursement we may receive for our products.
- A significant breakdown, security breach or interruption affecting our internal computer systems, or those used by our third-party research collaborators, may compromise the confidentiality of our financial or proprietary information, result in material disruptions of our products and operations and adversely affect our reputation.
- We may be unsuccessful at hiring and retaining qualified personnel.
- Adverse circumstances caused by disease epidemics or pandemics, such as Coronavirus Disease 2019, or COVID-19, a novel coronavirus first detected in 2019;

Please also refer to the section entitled “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as such risk factors may be amended, updated or modified periodically in our reports filed with the U.S. Securities and Exchange Commission (the “SEC”) for further information on these and other risks affecting us.

We caution you not to place undue reliance on forward-looking statements because our future results may differ materially from those expressed or implied by them. We do not intend to update any forward-looking statement, whether written or oral, relating to the matters discussed in this Quarterly Report on Form 10-Q, except as required by law.

Our research programs in neurodegeneration benefit from longstanding scientific and financial support from the National Institutes of Health (“NIH”). The contents of this Quarterly Report on Form 10-Q are solely our responsibility and do not necessarily represent any official views of NIH.

## Overview

Cassava Sciences, Inc. is a clinical-stage biotechnology company based in Austin, Tx. Our mission is to detect and treat neurodegenerative diseases, such as Alzheimer’s disease. Our novel science is based on stabilizing – but not removing – a critical protein in the brain.

Over the past 10 years, we have combined state-of-the-art technology with new insights in neurobiology to develop novel solutions for Alzheimer’s disease and other neurodegenerative diseases. Our strategy is to leverage our unique scientific/clinical platform to develop a first-in-class program for treating neurodegenerative diseases, such as Alzheimer’s.

We currently have two clinical-stage biopharmaceutical assets under development:

- our lead therapeutic product candidate, called simufilam, is a novel treatment for Alzheimer’s disease; and
- our lead investigational diagnostic product candidate, called SavaDx, is a novel way to detect the presence of Alzheimer’s disease from a small sample of blood, possibly years before the overt appearance of clinical symptoms.

Our scientific approach for the treatment of Alzheimer’s disease seeks to simultaneously improve *both* neurodegeneration and neuroinflammation. We believe our ability to improve multiple vital functions in the brain represents a new, different and crucial approach to address Alzheimer’s disease.

Our lead therapeutic product candidate, simufilam, is a proprietary small molecule (oral) drug. Simufilam targets an altered form of a protein called filamin A (FLNA) in the Alzheimer’s brain. Published studies have demonstrated that the altered form of FLNA causes neuronal dysfunction, neuronal degeneration and neuroinflammation.

We believe simufilam improves brain health by reverting altered FLNA back to its native, healthy conformation, thus countering the downstream toxic effects of altered FLNA. We have generated and published experimental and clinical evidence of improved brain health with simufilam. Importantly, simufilam is not dependent on clearing amyloid from the brain. Since simufilam has a unique mechanism of action, we believe its potential therapeutic effects may be additive or synergistic with that of other therapeutic candidates aiming to treat neurodegeneration.

Simufilam has demonstrated a multitude of beneficial effects in animal models of disease, including normalizing neurotransmission, decreasing neuroinflammation, suppressing neurodegeneration, and restoring memory and cognition.

Simufilam and SavaDx were both discovered and designed in-house and were characterized by our academic collaborators during research activities that were conducted from approximately 2008 to date. We own exclusive, worldwide rights to these drug assets and related technologies, without royalty obligations to any third party. Our patent protection with respect to simufilam and use of simufilam for Alzheimer’s disease and other neurodegenerative disease currently runs through 2033 and includes six issued patents and related patent filings and applications. In addition, we have patent protection with respect to simufilam for use in treating certain cancers that runs through 2034.



We currently have no patents or patent applications with respect to SavaDx, which is protected in the United States by trade secrets, know-how and other proprietary rights technology.

Alzheimer's disease is a progressive neurodegenerative disorder that affects cognition, function and behavior. There are no disease-modifying drug therapies to treat the disease. As of 2020, there were approximately 50 million people worldwide living with dementia, a figure expected to increase to 150 million by 2050 and the annual global cost of dementia is now above \$1 trillion, according to *Alzheimer's Disease International*, a charitable organization. According to the non-profit *Alzheimer's Association*, Alzheimer's disease is expected to nearly triple in the U.S. between now and 2050. If this occurs, there is potential for Alzheimer's disease to cause a major financial drain on the national economy.

#### **Phase 2a Study**

In 2019, we completed a small, first-in-patient, clinical-proof-of-concept, open-label Phase 2a study of simufilam in the U.S., with substantial support from the *National Institute on Aging* (NIA), a division of the NIH. Treatment with simufilam for 28 days significantly improved key biomarkers of Alzheimer's pathology, neurodegeneration and neuroinflammation ( $p < 0.001$ ). Biomarkers effects were seen in all patients in both cerebrospinal fluid (CSF) and plasma.

#### **Phase 2b Study**

In September 2020, we announced final results of a Phase 2b study with simufilam in Alzheimer's disease. In this clinical study funded by the NIH, Alzheimer's patients treated with 50 mg or 100 mg of simufilam twice-daily for 28 days showed statistically significant ( $p < 0.05$ ) improvements in CSF biomarkers of disease pathology, neurodegeneration and neuroinflammation, versus Alzheimer's patients who took placebo. In addition, Alzheimer's patients treated with simufilam showed improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo (Effect Size 17-46%). Cognitive improvements correlated most strongly ( $R^2 = 0.5$ ) with decreases in levels of P-tau181.

#### **Clinical Strategy Around Open-label Study**

Much of the value of our open-label study is to gain data to support simufilam's long-term safety profile in patients. Interim efficacy data from an open-label study has limitations compared to efficacy data from a fully completed, large, randomized controlled clinical trial, or from a fully enrolled open-label study.

We believe there is logic to conducting an open-label study prior to conducting a large, expensive Phase 3 clinical testing program. First, this is a standard clinical method of demonstrating drug safety. Second, we believe that if an experimental drug for Alzheimer's shows *no* treatment benefits in a well-designed open-label study, then there is no chance that drug will succeed in Phase 3 clinical testing. Of course, the opposite is not true: encouraging treatment effects in an open-label study is not proof of drug efficacy, nor can encouraging treatment effects predict clinical success in a Phase 3 program.

In short, we believe a well-designed, open-label study is an exercise in prudent risk-management. Clinical results may serve as a tool to help inform and manage the inherent risks and uncertainties of drug development prior to undertaking a large, expensive Phase 3 clinical testing program.

#### **Open-label Study Strategy**

In March 2020, we initiated a long-term, open-label study to evaluate simufilam in patients with Alzheimer's disease. This study is funded by a research grant award from the National Institutes of Health (NIH). The study is intended to monitor the long-term safety and tolerability of simufilam 100 mg twice-daily for 12 or more months. Another study objective is to measure changes in cognition using ADAS-Cog, a standard test of cognition in Alzheimer's disease. The study protocol has pre-specified cognition measurements at 6, 9 and 12 months. This study also uses the Neuropsychiatric Inventory (NPI) to assess the presence and severity of dementia-related behavior. ADAS-Cog and NPI scales are both widely used clinical tools in trials of Alzheimer's disease.

In June 2021, the open-label study reached its target enrollment of 150 subjects with mild-to-moderate Alzheimer's disease. By physician and patient request, clinical sites may continue to enroll additional subjects up through the initiation of the Company's Phase 3 pivotal program of simufilam.

In February 2021, we announced results of a preplanned interim analysis of our open-label study with simufilam. This interim analysis summarized clinical data in the first 50 patients who have completed at least 6 months of drug treatment. Patients' cognition and behavior scores both improved following six months of simufilam treatment, with no safety issues. Six months of simufilam treatment improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6. In these same patients, simufilam also improved dementia-related behavior, such as anxiety, delusions and agitation, by 1.3 points on the Neuropsychiatric Inventory, a 29% mean improvement from baseline to month 6.

In July 2021, we announced results of another preplanned interim analysis of our open-label study with simufilam. This interim analysis summarized clinical data on the first 50 patients who have completed at least 9 months of drug treatment. Patients' cognition and behavior scores both improved following six months of simufilam treatment, with no safety issues. Nine months of simufilam treatment improved cognition scores by 3.0 points on ADAS-Cog11, an 18% mean improvement from baseline to month 9 ( $p < 0.001$ ). Figure 1.

**Figure 1. Cognition Results**

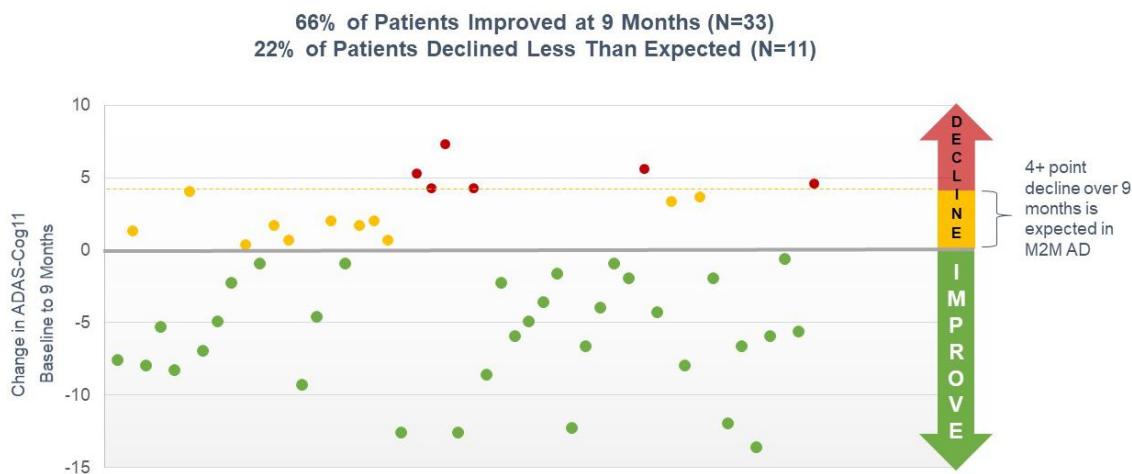
**ADAS-Cog11 scores improved 3 points at 9 months in the first 50 subjects.**



Alzheimer's is a progressive disease. Cognition will always decline over time. Historical controls indicate that in patients with mild-to-moderate Alzheimer's disease, cognition scores decline 4+ points on ADAS-Cog over 9 months, as reported by the science literature, and, more recently, by Biogen, Inc. In 2020, Biogen reported a 5.2-point decline over 18 months on ADAS-Cog in placebo patients with early Alzheimer's disease in two Phase 3 studies with their drug, aducanumab.

Despite an expectation of cognitive decline, simufilam improved ADAS-Cog scores in 66% of patients at 9 months. An additional 22% of patients declined less than an expected 4+ point decline at 9 months. Cognition outcomes suggest simufilam's treatment effects were broad-based. Figure 2.

**Figure 2. Individual Patient Changes in ADAS-Cog (N=50)**



Alzheimer's is often accompanied by behaviors disorders, such as anxiety, agitation or delusions. These may become more frequent as disease progresses. Simufilam reduced dementia-related behavior at 9 months on the Neuropsychiatric Inventory (NPI), a clinical tool widely used to measure changes in dementia-related behavior.

- At baseline, 34% of study subjects had no neuropsychiatric symptoms.
- At month 6, 38% of study subjects had no neuropsychiatric symptoms.
- At month 9, over 50% of study subjects had no neuropsychiatric symptoms.

The safety profile of simufilam in the interim analysis is consistent with prior human studies. There were no drug-related serious adverse events. Adverse events were mild and transient.

In July 2021, we also announced positive biomarker data from our open-label study. Biomarkers are objective biological data. There are no placebo effects.

A key objective of this bioanalysis was to measure changes in levels of biomarkers in patients before and after 6 months of treatment with open label simufilam. Biomarker data were analyzed from cerebrospinal fluid (CSF) collected from 25 patients with mild-to-moderate Alzheimer's disease who are enrolled in the open-label study and who agreed to undergo a lumbar puncture at baseline and again after 6 months of treatment. All bioanalyses were conducted blind by an outside lab.

Simufilam robustly improved all measured CSF biomarkers.

Cerebrospinal fluid (CSF) biomarkers of disease pathology, t-tau and p-tau181, decreased 38% and 18%, respectively (both  $p < 0.00001$ ). CSF biomarkers of neurodegeneration, neurogranin and NfL, decreased 72% and 55%, respectively (both  $p < 0.00001$ ). CSF biomarkers of neuroinflammation, sTREM2 and YKL-40, decreased 65% and 44% (both  $p < 0.00001$ ). All p-values are baseline vs. 6-month levels by paired t-test. Figure 3.

Core markers of Alzheimer's pathology are total tau (T-tau), phosphorylated tau (P-tau181), and amyloid beta42 (A $\beta$ 42). In Alzheimer's, tau levels are elevated and A $\beta$ 42 is low.

- T-tau decreased 38% ( $p < 0.00001$ )
- P-tau181 decreased 18% ( $p < 0.00001$ )
- CSF A $\beta$ <sub>42</sub> increased 84% ( $p < 0.00001$ )

Elevated CSF levels of two proteins, neurogranin (Ng) and neurofilament Light Chain (NfL) indicate neurodegeneration.

- Ng decreased 72% ( $p < 0.00001$ )
- NfL decreased 55% ( $p < 0.00001$ )

Elevated levels of marker YKL-40 indicate neuroinflammation.

- YKL-40 decreased 44% ( $p < 0.00001$ )

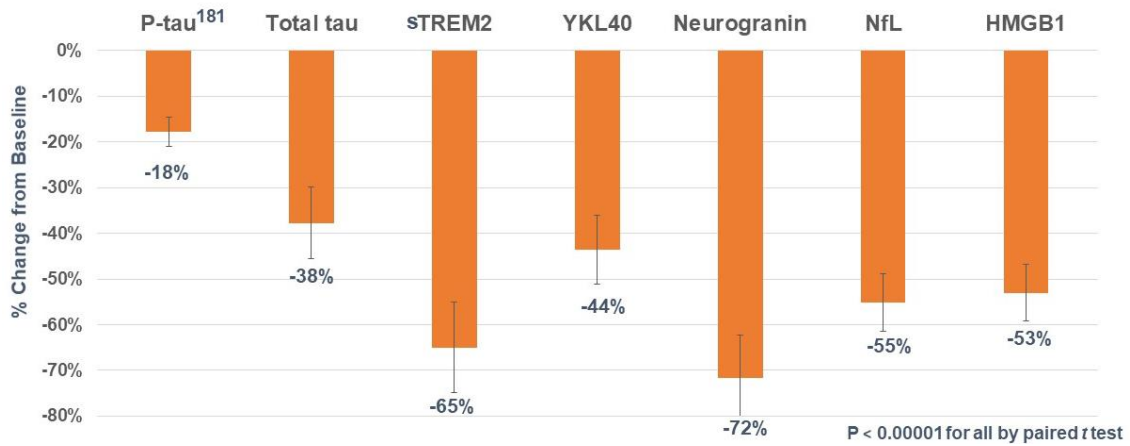
sTREM2 is a biomarker of microglia-induced neuroinflammation that has commanded substantial recent attention from researchers for its role in Alzheimer's and frontotemporal dementia.

- sTREM2 decreased 65% ( $p < 0.00001$ )

HMGB1 protein, is a damage-related protein sometimes called a 'danger molecule' because it triggers additional neuroinflammation and loss of neurons.

- HMGB1 decreased 53% ( $p < 0.00001$ )

**Figure 3. Significant Decreases in CSF Biomarkers at Month 6**

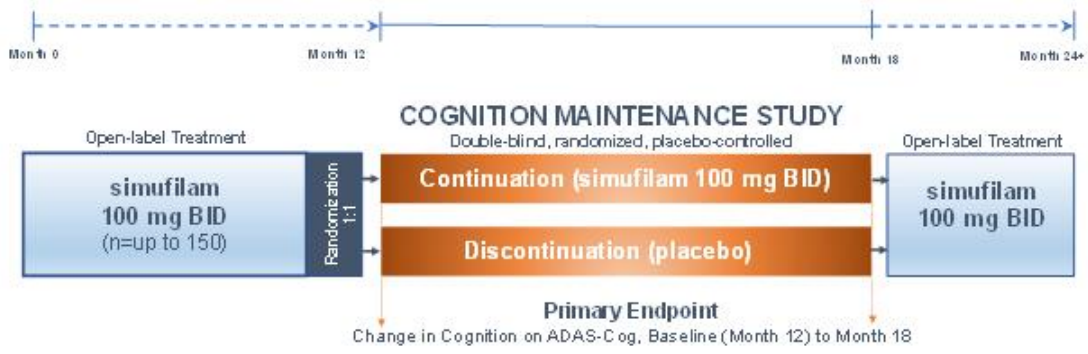


### Cognition Maintenance Study

In May 2021, we initiated a double-blind, randomized, placebo-controlled study in patients with mild-to-moderate Alzheimer's disease. Patients who have completed at least one year of open-label treatment with simufilam qualify to enroll in the *Cognition Maintenance Study* (CMS). Study subjects in the CMS are randomized (1:1) to simufilam or placebo for six months. The CMS is designed to compare simufilam's effects on cognition in Alzheimer's patients

who continue with drug treatment versus patients who discontinue drug treatment. Figure 4. The target enrollment for the CMS is 100 subjects or more; as of mid-June 2021, approximately 30 subjects were enrolled.

**Figure 4. Cognition Maintenance Study Design**



### **End-of-Phase 2 (EOP2) Meeting with FDA**

In January 2021, we held an End-of-phase 2 (EOP2) meeting for simufilam with the U.S Food and Drug Administration (FDA). The purpose of this EOP2 was to gain general agreement around key elements of a pivotal Phase 3 program to treat Alzheimer's disease dementia. FDA attendees included Robert Temple, MD, Deputy Center Director for Clinical Science and Senior Advisor in the Office of New Drugs; Billy Dunn, MD, Director, Office of Neuroscience; Eric Bastings, MD, Director, Division of Neurology, and others.

In February 2021, we announced the successful completion of our EOP2 meeting. Official meeting minutes confirm that we and FDA are aligned on key elements of a Phase 3 clinical program for simufilam. FDA has agreed that the completed Phase 2 program, together with an upcoming and well-defined Phase 3 clinical program, are sufficient to show evidence of clinical efficacy for simufilam in Alzheimer's disease. There is also agreement that the use of separate clinical scales to assess cognition (ADAS-cog<sup>1</sup>) and function (ADCS-ADL<sup>2</sup>) are appropriate co-primary endpoints of efficacy. A clinical scale that combines cognition and function, such as iADRS<sup>3</sup>, is a secondary efficacy endpoint.

Agreements reached during the EOP2 meeting show a clear path forward for advancing simufilam into Phase 3 studies. As a result, we expect to initiate a pivotal Phase 3 program with simufilam in Alzheimer's disease in the second half of 2021.

### **Phase 3 Drug Supply**

In March 2021, we announced we had entered into a drug supply agreement with Evonik Industries AG for simufilam. Under the agreement, Evonik will supply us with large-scale, clinical-grade quantities of simufilam. Evonik is one of the world's largest contract development and manufacturing organizations for pharmaceutical ingredients.

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<sup>1</sup> ADAS-Cog = *The Alzheimer's Disease Assessment Scale – Cognitive Subscale, a measure of cognition*

<sup>2</sup> ADCS-ADL = *Alzheimer's Disease Cooperative Study – Activities of Daily Living, a measure of health function*

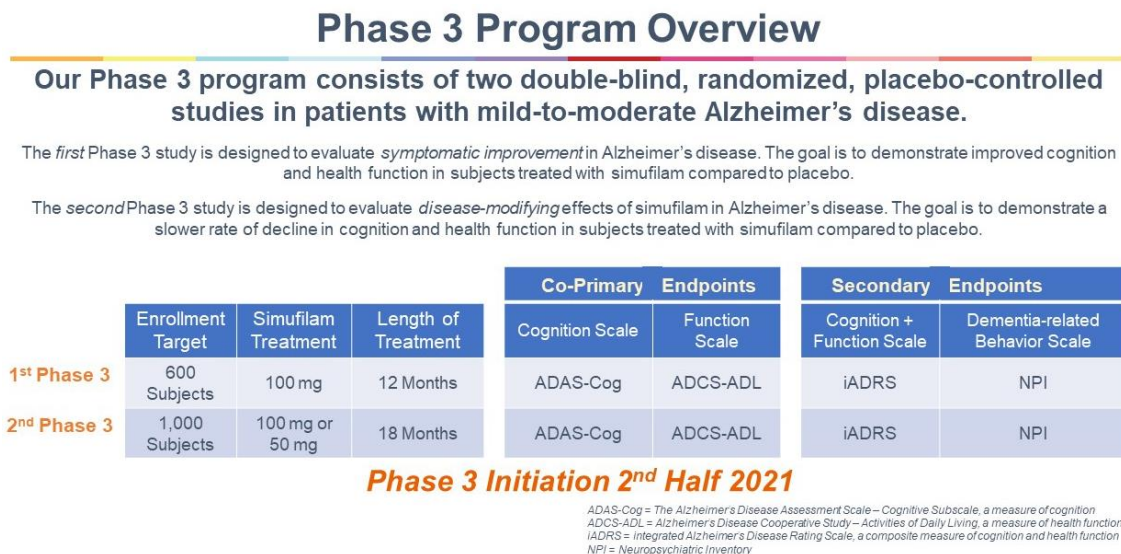
<sup>3</sup> iADRS = *integrated Alzheimer's Disease Rating Scale, a composite measure of cognition and health function*

### Phase 3 Clinical Program

We plan to initiate a Phase 3 program of simufilam in Alzheimer’s disease. The Phase 3 program consists of two large, double-blind, randomized, placebo-controlled studies in patients with mild-to-moderate Alzheimer’s disease dementia. In June 2021, we announced the selection of Premier Research International as our clinical research organization (CRO) to help conduct the Phase 3 clinical program of simufilam for Alzheimer’s disease.

We expect to initiate the Phase 3 program in Q4 2021. Figure 5.

Figure 5. Phase 3 Program Overview



### SavaDx

Our diagnostic effort, called SavaDx, is a clinical-stage program focused on detecting the presence of Alzheimer’s disease from a small sample of blood, possibly years before the overt appearance of clinical symptoms. We are developing SavaDx as a fast, accurate and quantitative blood-based investigational biomarker/diagnostic to detect and monitor Alzheimer’s disease. The goal is to make the detection of Alzheimer’s disease as simple as getting a blood test. There is no patent protection for SavaDx in the U.S., but we believe this product candidate is protected by trade secrets, know-how and other proprietary rights technology. The SavaDx program is substantially funded by a research grant award from the National Institutes of Health (NIH).

In blinded studies, SavaDx detected >10-fold differences between patients with Alzheimer’s and age-matched normal controls or young cognitively intact subjects (N=232).

In July 2021, we announced positive clinical data with SavaDx when used to measure plasma levels of altered filamin A before and after simufilam treatment in patients with Alzheimer’s disease. In a Phase 2b randomized, controlled trial sponsored by the National Institutes of Health (NIH), simufilam significantly reduced plasma levels of altered filamin A in Alzheimer’s patients treated for 28 days. Plasma levels of p-tau181 also dropped significantly in these same patients.

Simufilam 100 mg and 50 mg reduced plasma levels of altered filamin A by 48% (p=0.003) and 44% (p=0.02) respectively, versus placebo. Additionally, simufilam 100 mg and 50 mg reduced plasma levels of p-tau181 by 17% (p=0.01) and 15% (p=0.02) respectively, versus placebo. Plasma p-tau181 is a biomarker that is known to be elevated in Alzheimer’s disease.

### Impact of COVID-19 on our Business

In these times of pandemic, our top priorities are to protect the health, well-being, and safety of our employees and partners, while still focusing on the key drivers of our business. Despite COVID-19, we believe we remain on-track to achieve our major strategic objectives for 2021 with simufilam. We have not experienced major disruptions across our drug manufacturing operations or supply of materials. Our broad spectrum of technical consultants, scientific advisors and service providers continue to provide timely services. We have adapted flexible business practices, such as remote work arrangements and temporary travel restrictions, to insure we continue to operate safely and cautiously while also meeting our public health responsibilities. We recognize the pandemic has created a dynamic and uncertain situation in the national economy. We continue to closely monitor the latest information to make timely, informed business decisions and public disclosures regarding the potential impact of pandemic on our operations. However, the scope of pandemic is unprecedented and its long-term impact on our operations cannot be reasonably estimated at this time.

### Financial Overview

We have yet to generate any revenues from product sales. We have an accumulated deficit of \$183.6 million at June 30, 2021. These losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs and general corporate expenses. Research and development activities include costs of preclinical and clinical trials as well as clinical supplies associated with our product candidates. Salaries and other personnel-related costs include stock-based compensation associated with stock options and other equity awards granted to employees and non-employees. Our operating results may fluctuate substantially from period to period as a result of the timing of reimbursement from NIH grants, preclinical activities, enrollment rates of clinical trials for our product candidates and our need for clinical supplies.

We expect to continue to use significant cash resources in our operations for the next several years. Our cash requirements for operating activities and capital expenditures may increase substantially in the future as we:

- initiate a large-scale drug manufacturing campaign for simufilam;
- plan to initiate a Phase 3 clinical program with simufilam;
- conduct other preclinical and clinical studies for our product candidates;
- plan to seek regulatory approvals for our product candidates;
- develop, formulate, manufacture and commercialize our product candidates;
- implement additional internal systems and develop new infrastructure;
- acquire or in-license additional products or technologies, or expand the use of our technology;
- maintain, defend and expand the scope of our intellectual property
- hire additional personnel; and
- expand our office facilities to accommodate growth in personnel and R&D activities.

Product revenue will depend on our ability to receive regulatory approvals for, and successfully market, our product candidates. If our development efforts result in regulatory approval and successful commercialization of our product candidates, we will generate revenue from direct sales of our drugs and/or, if we license our drugs to future collaborators, from the receipt of license fees and royalties from sales of licensed products. We conduct our research and development programs through a combination of internal and collaborative programs. We rely on arrangements with universities, our collaborators, contract research organizations and clinical research sites for a significant portion of our product development efforts.

We focus substantially all of our research and development efforts in the area of neurology. The following table summarizes expenses which have been reduced for reimbursements received for NIH grants (in thousands):

|   | Three months ended<br>June 30, |          | Six months ended<br>June 30, |          |
|---|--------------------------------|----------|------------------------------|----------|
|   | 2021                           | 2020     | 2021                         | 2020     |
| Research and development expenses - gross | \$ 4,787                       | \$ 1,688 | \$ 7,892                     | \$ 3,574 |
| Less: Reimbursement from NIH grants       | 886                            | 1,097    | 1,462                        | 2,439    |
| Research and development expenses - net   | \$ 3,901                       | \$ 591   | \$ 6,430                     | \$ 1,135 |

Research and development expenses include compensation, contractor fees and supplies as well as allocated common costs. Contractor fees and supplies generally include expenses for preclinical studies and clinical trials and



costs for formulation and manufacturing activities. Other common costs include the allocation of common costs such as facilities. During the three months ended June 30, 2021 and 2020, we received \$0.9 million and \$1.1 million from NIH research grants, respectively. During the six months ended June 30, 2021 and 2020, we received \$1.5 million and \$2.4 million from NIH research grants, respectively. These reimbursements were recorded as a reduction to our research and development expenses.

Our technology has been applied across certain of our product candidates. Data, know-how, personnel, clinical results, research results and other matters related to the research and development of any one of our product candidates also relate to, and further the development of, our other product candidates. As a result, costs allocated to a specific drug candidate may not necessarily reflect the actual costs surrounding research and development of that product candidate due to cross application of the foregoing.

Estimating the dates of completion of clinical development, and the costs to complete development, of our product candidates would be highly speculative, subjective and potentially misleading. Pharmaceutical product candidates take a significant amount of time to research, develop and commercialize. The clinical trial portion of the development of a new drug alone usually spans several years. We expect to reassess our future research and development plans based on our review of data we receive from our current research and development activities. The cost and pace of our future research and development activities are linked and subject to change.

### **Critical Accounting Policies**

The preparation of our condensed financial statements in accordance with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and interest income in our condensed financial statements and accompanying notes. We evaluate our estimates on an ongoing basis, including those estimates related to agreements and research collaborations. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The following items in our condensed financial statements require significant estimates and judgments:

- *Research Contracts and Accruals.* We have entered into various research and development contracts with research institutions and other third-party vendors. Related payments are recorded as research and development expenses as incurred. We record accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, we analyze progress of the studies including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from our estimates. Our historical accrual estimates have not been materially different from actual costs.
- *2020 Cash Incentive Bonus Plan.* In 2020, we established the 2020 Cash Incentive Bonus Plan (the “Plan”) to incentivize Plan participants. Awards under the Plan are accounted for as liability awards under ASC 718, “Stock-based Compensation”. The fair value of each potential Plan award will be determined once a grant date occurs and will be remeasured each reporting period. Compensation expense associated with the Plan will be recognized over the expected achievement period for each Plan award, when a Performance Condition is considered probable of being met.

The Plan was established to promote the long-term success of the Company by creating an “at-risk” cash bonus program that rewards Plan participants with additional cash compensation in lockstep with significant increases in our market capitalization. The Plan is considered “at-risk” because Plan participants will not receive a cash bonus unless our market capitalization increases significantly and (1) we complete a merger or acquisition transaction that constitutes a sale of ownership of the Company or its assets (a Merger Transaction) or (2) the Compensation Committee of the Board (the Compensation Committee) determines the Company has sufficient cash on hand, as defined in the Plan, to render payment (each, a “Performance Condition”), neither of which may ever occur. Because of the inherent discretion and uncertainty regarding these requirements, we have concluded that a Plan grant date has not occurred as of June 30, 2021. No actual cash payments were authorized or made to participants under the Plan through June 30, 2021.

- Stock-based Compensation.* We recognize non-cash expense for the fair value of all stock options and other share-based awards. We use the Black-Scholes option valuation model to calculate the fair value of stock options, using the single-option award approach and straight-line attribution method. For all options granted, we recognize the resulting fair value as expense on a straight-line basis over the vesting period of each respective stock option, generally four years.

We have granted share-based awards that vest upon achievement of certain performance criteria, or Performance Awards. We multiply the number of Performance Awards by the fair value of our common stock on the date of grant to calculate the fair value of each award. We estimate an implicit service period for achieving performance criteria for each award. We recognize the resulting fair value as expense over the implicit service period when we conclude that achieving the performance criteria is probable. We periodically review and update as appropriate our estimates of implicit service periods and conclusions on achieving the performance criteria. Performance Awards vest and common stock is issued upon achievement of the performance criteria.

- Income Taxes.* We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax balances are adjusted to reflect tax rates based on currently enacted tax laws, which will be in effect in the years in which the temporary differences are expected to reverse. We have accumulated significant deferred tax assets that reflect the tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Realization of certain deferred tax assets is dependent upon future earnings. We are uncertain about the timing and amount of any future earnings. Accordingly, we offset these deferred tax assets with a valuation allowance.

We account for uncertain tax positions in accordance with ASC 740, "Income Taxes", which clarifies the accounting for uncertainty in tax positions. These provisions require recognition of the impact of a tax position in our condensed financial statements only if that position is more likely than not of being sustained upon examination by taxing authorities, based on the technical merits of the position. Any interest and penalties related to uncertain tax positions will be reflected as a component of income tax expense.

## **Results of Operations – Three and Six Months Ended June 30, 2021 and 2020**

### *Research and Development Expense*

Research and development expenses consist primarily of costs of drug development work associated with our product candidates, including:

- Pre-clinical testing,
- clinical trials,
- clinical supplies and related formulation and design costs, and
- compensation and other personnel-related expenses.

Research and development expenses were \$3.9 million and \$0.6 million during the three months ended June 30, 2021 and 2020, respectively. This 560% increase was due primarily to costs related to the manufacturing of clinical trial supplies in anticipation of launching a Phase 3 clinical program in simufilam, costs of an on-going open-label study in simufilam, as well as increased personnel costs compared to the prior year.

Research and development expenses were \$6.4 million and \$1.1 million during the six months ended June 30, 2021 and 2020, respectively. The 467% increase was due primarily to costs related to the manufacturing of clinical trial supplies in anticipation of launching a Phase 3 clinical program in simufilam, costs of an on-going open-label study in simufilam, increased personnel costs, as well as a decrease in grant funding received from NIH compared to the prior year. During the six months ended June 30, 2021 and 2020, we received \$1.5 million and \$2.4 million from research grants from NIH, respectively.

We expect research and development expense to increase significantly in future periods as we continue to hire new personnel, manufacture drug supply, continue our development efforts and launch a Phase 3 clinical program in simufilam.

#### *General and Administrative Expense*

General and administrative expenses consist of personnel costs, allocated expenses and other expenses for outside professional services, including legal, human resources, audit and accounting services. Personnel costs consist of salaries, bonus, benefits and stock-based compensation. Allocated expenses consist primarily of facility costs. We incur expenses associated with operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq, additional insurance expenses, additional audit expenses, investor relations activities, Sarbanes-Oxley compliance expenses and other administrative expenses and professional services.

General and administrative expenses were \$1.2 million and \$0.8 million during the three months ended June 30, 2021 and 2020, respectively. The 51% increase was due primarily to higher annual shareholder meeting and insurance costs in 2021 compared to the prior year.

General and administrative expenses were \$2.2 million and \$1.6 million during the six months ended June 30, 2021 and 2020, respectively. The 40% increase was due primarily to higher annual shareholder meeting and insurance costs in 2021 compared to the prior year.

We expect our general and administrative expenses to increase in future periods due to higher operating costs such as insurance, office space and information technology related expenses.

#### *Gain on Sale of Property and Equipment*

There were no sales of property and equipment during the three and six months ended June 30, 2021.

During the three months ended June 30, 2020, we sold surplus manufacturing equipment to an independent third party and received proceeds totaling \$260,000. During the six months ended June 30, 2020, we sold surplus manufacturing equipment to an independent third party and received proceeds totaling \$360,000.

We do not expect any future gains on sales of property and equipment.

#### *Interest Income*

Interest income was \$13,000 and \$27,000 during the three months ended June 30, 2021 and 2020, respectively. Interest income was \$20,000 and \$99,000 during the six months ended June 30, 2021 and 2020, respectively. The decrease in interest income was due to lower interest rates, which more than offset additional interest from increases in our cash balances compared to the prior periods.

We expect interest income to decrease in 2021 compared to 2020 due to decreases in interest rates.

#### *Liquidity and Capital Resources*

Since inception, we have financed our operations primarily through public and private stock offerings, payments received under collaboration agreements and interest earned on our cash and cash equivalents balances. We intend to continue to use our capital resources to fund research and development activities, capital expenditures, working capital requirements and other general corporate purposes. As of June 30, 2021, cash and cash equivalents were \$278.3 million.

#### *2021 Registered Direct Offering*

On February 12, 2021, we completed a common stock offering pursuant to which certain investors purchased 4,081,633 shares of common stock at a price of \$49.00 per share. Net proceeds of the offering were approximately \$189.8 million after deducting offering expenses.

#### *Common Stock Warrants*

In August 2018, we issued warrants to purchase up to an aggregate of 9.1 million shares of common stock in conjunction with an offering of our common stock.

We did not receive any proceeds from exercise of common stock warrants during the three months ended June 30, 2021. During the three months ended June 30, 2020, we received proceeds of \$0.2 million from the exercise of 0.2 million shares pursuant to warrants.

During the six months ended June 30, 2021, we received proceeds of \$0.7 million from the exercise of 0.6 million shares pursuant to warrants. During the six months ended June 30, 2020, we received proceeds of \$3.8 million from the exercise of 3.1 million shares pursuant to warrants.

There were no remaining common stock warrants outstanding as of June 30, 2021.

#### ***At-the-Market Common Stock Offering***

In March 2020, we established an at-the-market offering program (“ATM”) to sell, from time to time, shares of our common stock having an aggregate offering price of up to \$100 million in transactions pursuant to a shelf registration statement that was declared effective by the SEC on May 5, 2020. We are obligated to pay a commission of 3.0% of the gross proceeds from the sale of shares of common stock in the offering. We are not obligated to sell any shares in the offering.

There were no common stock sales under the ATM during the three and six months ended June 30, 2021 and 2020.

#### ***NIH Research Grant Awards***

Our programs have been supported by NIH under multiple research grant awards. Strong, long-term support from NIH has allowed us to advance our two lead product candidates, simufilam and SavaDx, into clinical development.

In May 2021, we were awarded a new research grant award from NIH of up to \$2.7 million to support clinical readiness activities in support of an upcoming Phase 3 program with simufilam. In April 2020, we were awarded a research grant from NIH of up to \$2.5 million. In March 2020, we were awarded a supplemental research funding grant from NIH of up to \$374,000. These non-dilutive research grants are intended to strengthen our clinical program of simufilam, our investigational drug to treat Alzheimer’s disease. All of our NIH research grant awards are paid out on a reimbursement basis and require milestone-based technical progress.

#### ***2020 Cash Incentive Bonus Plan Obligations***

On August 26, 2020, the Board approved the 2020 Cash Incentive Bonus Plan (the Plan). The Plan was established to promote the long-term success of the Company by creating an “at-risk” cash bonus program that rewards Plan participants with additional cash compensation in lockstep with significant increases in the Company’s market capitalization. The Plan is considered “at-risk” because Plan participants will not receive a cash bonus unless the Company’s market capitalization increases significantly and certain other conditions specified in the Plan are met. Specifically, Plan participants will not be paid any cash bonuses unless (1) the Company completes a merger or acquisition transaction that constitutes a sale of ownership of the Company or its assets (a Merger Transaction) or (2) the Compensation Committee determines the Company has sufficient cash on hand, as defined in the Plan. Plan participants will be paid all earned cash bonuses in the event of a Merger Transaction.

The Company’s market capitalization, including all outstanding stock options, was \$89.4 million at the inception of the Plan on August 26, 2020. If the Company were to exceed a \$5 billion market capitalization for no less than 20 consecutive trading days, and conditions noted above for payment are met, all Plan milestones would be deemed achieved, in which case total cash bonus awards would range from a minimum of \$139.1 million up to a hypothetical maximum of \$322.3 million.

The Company’s potential financial obligation to plan participants at June 30, 2021 totaled \$7.3 million, based upon the achievement of one Plan milestone in the Company’s market capitalization in 2020. No actual cash bonus payments have been made to any Plan participant, as the Company has not yet satisfied all the conditions necessary for amounts to be paid under the Plan. During the six months ended June 30, 2021, the Company’s market capitalization increased substantially. These increases triggered the achievement of 10 additional Plan milestones.

Collectively, the achievement of such milestones could trigger potential Company obligations to Plan participants ranging from a minimum of \$81.0 million up to a hypothetical maximum of \$195.0 million, with exact amounts to be determined by the Compensation Committee and contingent upon future satisfaction of a Performance Condition.

Subsequent to June 30, 2021, the Company achieved one additional Valuation Milestone triggering potential Company obligations to all Plan participants from a minimum of \$12.7 million up to a hypothetical maximum of \$30.0 million, to be determined by the Compensation Committee and contingent upon future satisfaction of a Performance Condition.

No actual cash payments have been made to participants under the Plan as of June 30, 2021, or through the filing date of this Form 10-Q.

#### **Use of Cash**

Net cash used in operating activities was \$7.4 million for the six months ended June 30, 2021, resulting primarily from the net loss reported of \$8.7 million and an increase in prepaid and other assets of \$2.2 million, partially offset by an increase in accrued development expense of \$1.7 million and accounts payable of \$1.0 million, as well as stock-based compensation expense of \$0.7 million.

Net cash used in operating activities was \$2.0 million for the six months ended June 30, 2020, resulting primarily from the net loss reported of \$2.3 million and a gain on sale of property and equipment of \$0.3 million, partially offset by stock-based compensation expense of \$0.5 million.

Net cash used in investing activities during the six months ended June 30, 2021 was \$73,000 for purchase of property and equipment.

Net cash provided by investing activities during the six months ended June 30, 2020 was \$360,000 for proceeds received from the sale of property and equipment.

Net cash provided by financing activities during the six months ended June 30, 2021 was \$192.3 million, consisting of \$189.8 million proceeds from our registered direct offering of common stock in February 2021, \$1.7 million from exercise of stock options and \$0.7 million proceeds from exercise of common stock warrants.

Net cash provided by financing activities during the six months ended June 30, 2020 was \$3.8 million, resulting from proceeds from exercise of common stock warrants.

#### **Leases**

We lease approximately 6,000 square feet of office space pursuant to a non-cancelable operating lease in Austin, TX that expires in April 2024. We also lease an additional 3,600 square feet of office space in Austin, Texas that expires on April 30, 2022.

On August 4, 2021, we completed the purchase of a two-building office complex in Austin, Texas, which will serve as our new corporate headquarters. This property is intended to accommodate our anticipated significant growth and expansion of our operations in the coming years. Company management expects to be hands-off with regards to property management. Maintenance, physical facilities, leasing, property management and other key responsibilities around property ownership will all be assumed by professional real-estate managers under long-term contract with the Company. The property purchase price was \$21.9 million, exclusive of closing costs, funded with cash on hand. The office complex measures approximately 90,000 rentable square feet. The property is currently 59% leased, before the effect of the Company occupying approximately 25% of the property in the near future. The seller is an independent third party not affiliated with the Company.

#### **Other Commitments**

We had non-cancellable commitments for the manufacture of simufilam totaling approximately \$1.9 million at June 30, 2021.

We have an accumulated deficit of \$183.6 million as of June 30, 2021. We expect our cash requirements to be significant in the future. The amount and timing of our future cash requirements will depend on regulatory and market acceptance of our drug candidates, the resources we devote to researching and developing, formulating, manufacturing,

commercializing and supporting our products and other corporate needs. We believe that our current resources will be sufficient to fund our operations for at least the next 12 months. We may seek additional future funding through public or private financing in the future, if such funding is available and on terms acceptable to us. However, there are no assurances that additional financing will be available on favorable terms, or at all.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Per Item 305(e) of Regulation S-K, the information called for by this Item 3 is not required.

**Item 4. Controls and Procedures**

*Evaluation of disclosure controls and procedures.* Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer (as Principal Executive Officer) and our Chief Financial Officer (as Principal Financial Officer) have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

*Changes in internal control over financial reporting.* There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified during the three months ended June 30, 2021 that has materially affected, or is reasonable likely to materially affect, our internal control over financial reporting.

**PART II – OTHER INFORMATION****Item 1. Legal Proceedings**

None.

**Item 1A. Risk Factors**

*There have been no material changes to our risk factors from those disclosed under “Risk Factors” in Part I, Item 1A of our 2020 Annual Report on Form 10-K. The risks and uncertainties described in our 2020 Annual Report on Form 10-K are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially adversely affect our business, financial condition or results of operations.*

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

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

The following exhibits have been filed with this report:

| Exhibit No.           | Description  | Incorporated by Reference |             |             | Filed Herewith |
|-----------------------|--|---------------------------|-------------|-------------|----------------|
|                       |  | Form                      | Filing Date | Exhibit No. |                |
| <a href="#">3.1</a>   | <a href="#">Amended and Restated Certificate of Incorporation.</a>   | 10-Q                      | 7/29/2005   | 3.1         |                |
| <a href="#">3.2</a>   | <a href="#">Certificate of Amendment of Restated Certificate of Incorporation.</a>   | 8-K                       | 5/8/2017    | 3.1         |                |
| <a href="#">3.3</a>   | <a href="#">Certificate of Amendment of Restated Certificate of Incorporation.</a>   | 10-K                      | 3/29/2019   | 3.3         |                |
| <a href="#">3.4</a>   | <a href="#">Amended and Restated Bylaws of Cassava Sciences, Inc.</a>  | 8-K                       | 12/11/2020  | 3.1         |                |
| <a href="#">4.1</a>   | <a href="#">Specimen Common Stock Certificate.</a>   | 10-Q                      | 8/12/2019   | 4.1         |                |
| <a href="#">10.1</a>  | <a href="#">Form of Securities Purchase Agreement, dated February 10, 2021, by and between Cassava Sciences, Inc. and the purchasers named therein.</a>  | 8-K                       | 2/12/2021   | 10.1        |                |
| <a href="#">10.2*</a> | <a href="#">Master Services Agreement between Cassava Sciences, Inc. and Evonik Corporation, dated February 22, 2021.</a>  | 8-K                       | 3/11/2021   | 10.1        |                |
| <a href="#">10.3*</a> | <a href="#">Master Services Agreement between Cassava Sciences, Inc. and Premier Research International LLC, dated June 11, 2021</a>   |                           |             |             | X              |
| <a href="#">31.1</a>  | <a href="#">Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>  |                           |             |             | X              |
| <a href="#">31.2</a>  | <a href="#">Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>  |                           |             |             | X              |
| <a href="#">32.1</a>  | <a href="#">Certification of the Chief Executive Officer and the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a> |                           |             |             | X              |
| 101.INS               | XBRL Instance Document.  |                           |             |             | X              |
| 101.SCH               | XBRL Taxonomy Extension Schema Document.   |                           |             |             | X              |
| 101.CAL               | XBRL Taxonomy Extension Calculation Linkbase Document.   |                           |             |             | X              |
| 101.DEF               | XBRL Taxonomy Extension Definition Linkbase Document.  |                           |             |             | X              |
| 101.LAB               | XBRL Taxonomy Extension Labels Linkbase Document.  |                           |             |             | X              |
| 101.PRE               | XBRL Taxonomy Extension Presentation Linkbase Document.  |                           |             |             | X              |
| 104.                  | Cover Page Interactive Data File – the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.               |                           |             |             | X              |

\*Confidential portions of this document have been redacted as permitted by applicable regulations.



**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.

Cassava Sciences, Inc.  
\_\_\_\_\_  
(Registrant)

/s/ REMI BARBIER  
\_\_\_\_\_  
Remi Barbier,  
Chairman of the Board of Directors,  
President and Chief Executive Officer

Date: August 4, 2021

/s/ ERIC J. SCHOEN  
\_\_\_\_\_  
Eric J. Schoen,  
Chief Financial Officer

Date: August 4, 2021

Note: Certain identified information, [\*\*\*], in this Exhibit 10.3 has been excluded from the exhibit as that information (i) is not material and (ii) would likely result in competitive harm to the registrant if publicly disclosed.

## MASTER SERVICES AGREEMENT

This Master Services Agreement (the “Agreement”) is made and entered on this 11<sup>th</sup> day of June 2021, (the “Effective Date”), by and between **Cassava Sciences, Inc.**, a Delaware corporation with its principal address at 7801 N. Capital of Texas Hwy, Suite 260, Austin, TX 78731 (“Client”) and **Premier Research International LLC**, together with its Affiliates, with offices at 3800 Paramount Parkway, Suite 400, Morrisville, NC 27560-6949 (“Premier”), both hereinafter referred as a “Party” or collectively as the “Parties”.

**WHEREAS**, Premier is engaged in the business of providing services related to the implementation and management of clinical development programs for the pharmaceutical, biotechnology and medical device industries; and

**WHEREAS**, Client desires to engage Premier to perform such services in connection with certain pharmaceutical, medical device products and/or diagnostic products under development by or under control of Client.

**NOW THEREFORE**, in consideration of the premises and mutual promises and undertakings herein, the receipt and sufficiency of which are hereby acknowledged, the Parties intending to be legally bound do hereby agree as follows:

### 1.0 DEFINITIONS

- a. **Affiliates**: With respect to either Party, an Affiliate is any entity that is controlled by, controls, or is under common control with the Party named above.
  - b. **Amendment**: A written specification of changes to a Work Order that is agreed to by the Parties and authorized by signature of each Party’s authorized representative(s), in a format substantially similar to Exhibit B attached hereto.
  - c. **Applicable Laws**: All applicable international, multi-national, national, regional, state, provincial and local laws, regulations, rules, ordinances, requirements, directives, guidance, guidelines and policies.
  - d. **Budget for Services**: A component of a Work Order that delineates the estimated cost of the Services based upon the Project Specifications.
  - e. **Clinical Trial Agreement**: A contract for the implementation of a Study protocol between a Trial Site, a Sponsor, an Investigator, and Premier as the case may be, which includes obligations of all parties with respect to the conduct of a Study at the Trial Site.
  - f. **Deliverable**: Any document, database, report or other item specifically identified in a Work Order as an item to be produced by Premier and delivered to Client.
  - g. **Institutional Review Board (“IRB”)**: Any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of human subjects. The term has the same meaning as the phrase institutional review committee, independent ethics committee or ethics committee.
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- h. GCP or Good Clinical Practice: The standard defined in the ICH Harmonised Tripartite Guideline For Good Clinical Practice E6(R2) Current Step 4 version dated 9 November 2016 (including the Post Step 4 corrections) together with, for Services performed in the European Union, such other Good Clinical Practice requirements as are specified in Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001 relating to medicinal products for human use and in guidance published by the European Commission pursuant to such Directive and, when entered into force Regulation (EU) no 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC; and for Services performed in other jurisdictions, any analogous laws and/or regulations.
- i. Investigator(s): A person or persons responsible for the conduct of the clinical trial at a Trial Site. If a clinical trial is conducted by a team of individuals at a Trial Site, the Investigator is the responsible leader of the team and may be called the principal investigator.
- j. Milestone: An event associated with a specific date, for which a payment will be due, as set out in the Payment Schedule of any Work Order.
- k. Pass-Through Budget: A component of a Work Order that outlines the estimated costs of Pass-Through Expenses for goods and services incurred by Premier on behalf of Client, in connection with the performance of the Services.
- l. Payment Schedule: A component of a Work Order that describes the timing of payments due to be made for Services delivered and Pass-Through Expenses incurred.
- m. Premier Project Manager: The Premier representative assigned to lead the Premier project team, act as the principal liaison between Premier and Client, and provide general oversight in the delivery of Services with regard to a specific Work Order.
- n. Project Schedule: A component of a Work Order that outlines the project Milestones, estimated timelines and completion date for the Services based upon the Project Specifications.
- o. Project Specifications: A component of a Work Order that outlines the specific Services to be provided, assumptions used in preparing the Budget for Services, Pass-Through Budget and Project Schedule, and assignment of project-related responsibilities between the Parties.
- p. Regulatory Authority: A national, federal, state or local regulatory agency, department, bureau or other governmental entity (including, without limitation, the U.S. Food and Drug Administration and its foreign counterparts) responsible for the oversight and approval of the development and commercialization of drugs and biologics.
- q. Services: The services to be provided by Premier and its Subcontractors (if applicable) under this Agreement as specifically outlined in a Work Order or otherwise authorized by Client in writing.
- r. Study: A clinical trial performed at one or more investigative sites under the supervision of one or more Investigator(s) pursuant to a corresponding clinical trial protocol.
- s. Study Drug: The drug, compound, device or other material which is the subject of a Study under an individual Work Order.

- t. Subcontractor: An individual or company engaged by Premier to conduct or provide some elements of a Work Order, including without limitation, clinical laboratories, patient recruitment services, interactive voice recognition systems and other services.
- u. Trial Site(s): The location(s) where clinical Studies are actually conducted by Investigators.
- v. Work Order: A written specification of Services to be performed by Premier under this Agreement, including the Project Specifications, Project Schedule, contact information, Budget for Services, Pass-Through Budget, and Payment Schedule.

## 2.0 SERVICES

Premier, itself or through one of its Affiliates or Subcontractors (if applicable), will perform the Services as specified in this Agreement and any associated Work Order(s), in accordance with the terms and conditions of this Agreement. Premier will use reasonable efforts to perform the Services described in any Work Order issued hereunder and to meet all obligations and deadlines described in such Work Orders. The Parties will agree on all Services to be provided and the performance of those Services will be authorized in writing through the execution of a Work Order. Premier will not begin work on any Services without an agreement in writing.

Client will have the overall responsibility for the studies at all times and will manage all study related tasks which have not been specifically delegated to Premier as described in each Work Order. Client will, at its expense and as applicable, supply the drug for the timely completion of the clinical studies described in each Work Order. Client agrees to keep Premier fully informed at all times of relevant information known to Client which might influence the conduct of the study and the provision of Services.

Client acknowledges that Premier will require documents, drug supplies, data, records and cooperation by Client, investigators, and/or third party suppliers in order to properly perform the Services, and that Premier will not be liable for the failure of Client or any third party involved in a Study to supply such information or data to Premier.

All responsibility for the conduct of the study will remain with Client as defined in 21 CFR 312.52 or Directive 2001/20/EC, and when entered into force, Regulation (EU) No 536/2014, as applicable.

### 2.1 Work Orders

Premier will provide Services as specified in one or more Work Orders, which will be prepared in a format substantially similar to the form of Work Order, attached hereto as Exhibit A. Each Work Order will include detailed information with respect to a specific project, including Project Specifications, Project Schedule, Budget for Services, Pass-Through Budget, and Payment Schedule. Work Orders will become effective when signed by an authorized representative or representatives of both Parties as directed by the Work Orders. For purposes of this Agreement, the only authorized representatives of Client who are authorized to bind the Client to Work Orders are stated in Exhibit E. Premier will not change or deviate from the terms of a Work Order, including but not limited to any Study corresponding to such Work Order, except as provided in Section 2.2. In the event of any conflict between this Agreement and a Work Order, this Agreement shall control unless the Work Order expressly refers to the Parties' intent to alter the terms of this Agreement with respect to that Work Order.

### 2.2 Amendments

- A. Any changes to a Work Order or to any Study that is the subject of a Work Order including but not limited to changes to the Project Specifications, Project Schedule, Budget for Services or Pass-Through Budget, will be effective only when agreed upon by the Parties and documented in an Amendment to the Work

Order in a form substantially similar to that attached hereto as Exhibit B. Client agrees that Premier will not perform any out-of-scope work described in an Amendment until it is executed by both Parties.

B. Unanticipated Changes. The Parties agrees that some changes in costs incurred in the course of performing clinical research cannot be reasonably anticipated in advance. Upon identification by either Party of changes to the project assumptions or other unanticipated changes to the Project Specifications that will result in such material changes in costs, the Parties agree to negotiate in good faith an Amendment to accommodate increases or decreases to the Budget for Services, Project Schedule or Payment Schedule that are reasonably associated with any such adjustments. Amendments will be documented in writing in accordance with the terms of this Section 2.2. Such unanticipated changes may include, but are not limited to, any of the following:

- i. delays in receiving from Client technical information or Client's acceptance of documents submitted by Premier in the performance of its duties under this Agreement or any Work Order, or any other delay on the part of Client;
- ii. delay in receipt of regulatory approval from a regulatory agency, IRB or Ethics Committee;
- iii. delay in performance by a Subcontractor not selected by Premier;
- iv. delay in shipment or receipt of Study Drug, clinical samples and/or clinical supplies;
- v. delay due to changes in standard of care imposed by law, regulation or changes in medical practice affecting participating Trial Sites;
- vi. delay by reason of force majeure as defined herein;
- vii. Client requested additional services or changes to the Services or Study protocol;
- viii. delays due to questions received by either Party from regulatory agencies or ethics committees regarding submission materials that relate to characteristics of the Study Drug or protocol design;
- ix. delays due to any changes in Applicable Laws;
- x. changes in the enrollment rate of subjects;
- xi. changes to the Study protocol;
- xii. changes in amounts charged by third party suppliers or
- xiii. changes for any other reason agreed upon in writing by Client
- xiv. delays and changes caused by Premier or any of its subcontractors.

C. Amendment Process. All changes in scope will be recorded on a Change Order Log, which will include a description of the changes and associated costs, including any passthrough costs. If the value of the Change Order Log reaches \$/£/€ [\*\*\*], then Premier shall initiate a Change Notification Form (CNF) which shall detail all changes and associated costs and be presented to Client for approval and signature. If the value of the Change Order Log reaches \$/£/€[\*\*\*] of the total value of the original Work Order Budget then the Parties will enter into an Amendment substantially in the form set out in Exhibit B attached hereto. If there is a balance on a Change Order Log at the end of a Study, Premier shall invoice those costs under a final Amendment or termination letter. Premier will proceed with execution of any additional tasks set out in a CNF once Client has approved and signed the form. Invoicing for any additional costs will occur after an Amendment has been executed by the parties.

### **2.3 Project Staffing**

In performing the Services, Premier will assign personnel who are adequately trained, qualified and experienced to conduct the work as specified in a Work Order from one or more of its Affiliates located worldwide, as needed to perform the Services in accordance with the Work Order. Some assigned employees will be named as "Key Personnel" in each Work Order. Key Personnel are those personnel who will be responsible for oversight or management of the Services. Premier will use reasonable efforts to retain Key Personnel assigned to Client's Studies and will only replace Key Personnel in the event of unavailability due to prolonged absence, resignation or other circumstances beyond the control of Premier. If any assigned Key Personnel is to be replaced, the

replacement Key Personnel shall have at least the same level of experience and skills of the Key Personnel that is being replaced.

Client may make reasonable requests for replacement of Key Personnel for any bona fide business reason, including unsatisfactory performance or interpersonal conflicts. Premier will promptly (a) investigate any such matters and take appropriate action which may include (i) removing such Key Personnel from the provision of services for the Client or (ii) replacing such Key Personnel with a similarly qualified one; or (b) take such other action as is appropriate to prevent a recurrence. Premier will replace and train its Key Personnel at its own cost.

## **2.4 Use of Subcontractors**

Premier may use Subcontractors to conduct some elements of a Work Order. Premier will notify Client in advance of the name and its proposed use of each such Subcontractor. In the event that Client reasonably objects to any such Premier Subcontractor, Premier will replace the Premier Subcontractor with a Subcontractor acceptable to Client within a mutually agreeable timeframe at its own cost.

a. Client-Selected Subcontractors. In the event that Client requires Premier to use a specific subcontractor (hereinafter "Client Subcontractor"), Premier will not be responsible for the performance of the Client Subcontractor, and Client will manage the performance of the Client Subcontractor (unless Client instructs Premier in writing to do otherwise, and such management is included as a Service in a Work Order) and be responsible for any delays or changes to the Project Schedule or Budget for Services that result from the performance of the Client Subcontractor. Premier will notify Client promptly of any performance issues arising out of the use of any such Client Subcontractors. If Client engages a Client Subcontractor but requires that Premier manage or oversee the performance of the Client Subcontractor, then Client will supply Premier with a copy of the relevant contract with the Client Subcontractor. If Client requires that Premier contract with the Client Subcontractor, then Client hereby authorizes Premier to do so as agent on behalf of Client for the limited purpose of conducting a Work Order, provided, however, that Premier will not incur on behalf of Client any costs or expenses over \$[\*\*\*] without prior written permission of Client. Client will be responsible for the performance of a Client Subcontractor when the Client requests that Premier to contract directly with the Client Subcontractor.

b. Client remains responsible for any delays or changes to the Project Schedule or Budget for Services that result from the performance of Client engaged Client Subcontractor.

c. Premier-Selected Subcontractors. For Subcontractors selected and contracted directly by Premier (hereinafter "Premier Subcontractor"), Premier will be responsible for the performance of and will manage the performance of the Premier Subcontractor. Any subcontract with a Premier Subcontractor will be consistent with the terms and conditions of this Agreement, including without limitation, ownership of data and intellectual property under Article 10 and the obligations of confidentiality under Article 11.

## **2.5 Applicable Standards**

The Parties agree that Premier will provide the operational systems, processes and standard operating procedures to be used in performance of the Services unless specified otherwise in the Project Specifications. All Services will be conducted in accordance with GCP and Applicable Laws, including, but not limited to, all relevant personal data protection legislation.

## **2.6 Client-Provided Systems**

In the event that Client requires Premier to use Client's information systems and associated processes, Client will be responsible for all costs associated with installation and operation of the systems, including costs for hardware and software licenses, and for training of Premier personnel assigned to the project in the use of Client system(s). All risk associated with the use of a system provided by Client will be borne by Client.

## **2.7 Acceptance of Deliverables**

Delivery of any Deliverable shall be deemed accepted by Client, unless Client delivers notice of defect, deficiency or other problem within ninety (90) days of its receipt of the Deliverable. Any notice of deficiency must clearly specify the nature of the problem, deficiency or defect, and Premier will use all reasonable efforts to correct such problem, deficiency or defect promptly at its cost, subject to the limitation set forth in Section 14.3.

## **3.0 PAYMENT**

The Parties agree that the fees and other reimbursements that Premier will receive for performing the Services hereunder will be described in each Work Order and are subject to the following terms and conditions.

### **3.1 Compensation for Services**

- a. For Services provided, Client will pay Premier in accordance with the terms in this Section 3 of the Agreement and each applicable Work Order. Each Work Order will include a Budget for Services to be performed by Premier and will include the costs related to the Services to be provided. Premier will not exceed the total cost set forth in the Budget for Services in a given Work Order without the prior approval of Client in the form of an Amendment, as set out in Section 2.2 above. Client acknowledges that the Budget for Services presented in each Work Order is an estimate based upon the Project Specifications and Project Schedule.
- b. Retainer for study hold. In the event of a cessation of all activities of more than two (2) continuous weeks in the commencement or progress of a Study, whether for a study hold or other reason not caused by Premier, during which Client wishes to retain some or all members of the project team, Premier will charge a reasonable fee to retain the selected members of the project team. The fee will be based on then current hourly rates of retained staff, multiplied by the average projected weekly commitment of each such employee for the period of the suspension of Services, not to exceed 40 hours per member per week. In addition, when the period of suspension is over, the Client will pay costs incurred in retraining CRAs or other staff which were not retained during the period of the suspension of Services.
- c. Rebate and Discounts. The terms of Exhibit D, Volume Rebate and Non-Competitive Award Discounts shall apply, in the manner described therein.

### **3.2 Pass-Through Budget**

- a. Pass-Through Expenses. Pass-Through Expenses, include, but are not limited to, expenses for central labs, packaging and distribution of medication, printing and distribution of Case Report Forms, Institutional Review Board submission fees, (exclusive of investigator grants and reconciliation which are addressed in Section 3.3 below), incurred by Premier in the conduct and performance of the Services will be passed on without mark-up to Client for payment.

- b. In order to provide funding for Pass-Through Expenses, Client will make an initial payment to Premier of an amount described in the Work Order, at such time as shall be delineated in the Work Order. Premier will submit to Client monthly invoices for amounts incurred during the relevant billing period. The initial payment will be retained by Premier until the completion of the Services, at which time a reconciliation of expenses will be done to ensure that Client pays for only those expenses actually incurred. The initial payment, if any, will then be applied to the final invoice, if unpaid, and any remaining initial payment will be refunded to Client within thirty (30) days from the date of the final reconciliation.
- c. Client will reimburse reasonable and necessary travel expenses incurred by Premier employees in support of a Work Order, always in accordance with Premier's applicable Travel and Expense Policy (to be provided upon request), as shown on monthly invoices. Each invoice will include, as necessary, a summary of all Pass-Through Expenses.

### **3.3 Investigator Grants and Reconciliation**

In order to provide for timely payments to Investigators and/or Trial Sites, Client will make an initial payment to Premier of such amounts as are delineated in the Work Order. Premier will use the initial funds to make payments, in accord with the terms of the applicable Clinical Trial Agreement. Premier will submit to Client invoices in advance for estimated amounts to be paid to ensure that adequate funds are available to pay such fees and expenses. Client agrees that Premier will not make payments without sufficient funds available. The initial payment will be retained by Premier until the completion of the payments needed to pay such fees and expenses as outlined in the Clinical Trial Agreement. Once all fees and expenses have been paid, Premier will do a final reconciliation of all expenses to ensure that Client pays for only those expenses actually incurred. The initial payment, if any, will then be applied to the final invoice, if unpaid, and any remaining initial payment will be refunded to Client within thirty (30) days from the date of the final reconciliation. Bank charges or any other reasonable costs associated with making payments pursuant to Clinical Trial Agreements will be passed through to Client.

### **3.4 Invoices**

- a. Premier will submit invoices to Client according to the Payment Schedule described in the Work Order, accompanied by an itemized list of Services or Milestones achieved, and Pass-Through Expenses incurred. Premier will supply additional detail about any charges at Client's request. Any final payments specified in the Work Order will be invoiced upon completion of the project and delivery to Client of any final study databases, reports or other Deliverables as specified in the Project Specifications. Client shall have no obligation to pay Premier fees or reimburse expenses if these were incurred more than 365 days prior to first being invoiced to Client.
- b. All invoices under this Agreement will be forwarded to the Client representative designated in the relevant Work Order.
- c. All payments under this Agreement will be remitted to the Premier representative named in the Work Order, to the address and in the manner set forth in the Payment Schedule of the applicable Work Order. Timely payments of amounts due for undisputed Services and Pass-Through Expenses shall constitute a condition precedent to Premier's continued performance of its obligations under this Agreement.



### **3.5 Payment Terms**

Client agrees to pay for Services and Pass-Through Expenses in accordance with the Payment Schedule outlined in each Work Order or associated Amendment. All fees for Services and Pass-Through Expenses are exclusive of VAT (including non-refundable VAT), local taxes, charges or remittance fees, which Client will pay when applicable. Client will pay for all Services, Pass-Through Expenses and other correctly invoiced items, all at cost without further charge up, within thirty (30) days of invoice receipt, unless otherwise stated in a start-up agreement or Work Order, which may include different payment terms. All payments will be made in the currency noted in the Payment Schedule of the Work Order. Client will provide prompt notice to Premier of any disputed items in an invoice, and the Parties will work together to resolve the dispute in good faith and expeditiously according to Paragraph 27 (“Dispute Resolution”). In the event that disputed items are not resolved after resorting to the dispute resolution process, Premier reserves the right, at its sole discretion to suspend performance of the Services until such time that the overdue amounts are paid. Premier reserves the right to suspend work in the event that any undisputed invoices have not been resolved within thirty (30) days of the notification of the dispute. In addition, each Party shall be entitled to reimbursement from the other Party for any unpaid amount (including attorneys’ fees and court costs) incurred with respect to collection of overdue invoices that are not the subject of a *bona fide* dispute between the Parties.

### **3.6 Exchange Rate Fluctuation**

This provision will be applicable only when Premier performs Services in a region with a currency (“Local Currency”) that is different than the currency used for payment within the Work Order. Client and Premier agree that neither Client nor Premier should benefit or be disadvantaged by material variations in foreign currency exchange rates used in developing the budget for a Work Order or an Amendment (“Original Rates”) and the Local Currency rates on the dates of actual invoices, as published on OANDA.com.

Either Party may request a revision to the Original Rates if the Local Currency rates both one hundred and eighty (180) days in the past and the Local Currency rates at the time of the request vary from the Original Rates in an amount greater than +/- 5% (“Difference”). The Parties will negotiate in good faith to enter into an Amendment revising the Project Budget and Payment Schedule to reflect the allocation of the Difference and specifying new Original Rates. Any such revision will be based on the current Local Currency rates. Currency rates will be adjusted no more than twice per year. The currency revision will be applicable to billings invoiced after the date of the request for a revision of future billings. No such changes will have a retroactive effect to invoices paid prior to the request for currency adjustment. In the event Premier incurs a pass-through cost in a currency other than the contract currency, the Parties shall determine the amount payable based on an average conversion rate as reported on Oanda.com in the prior month.

### **3.7 Long Term Studies**

In cases where the project duration exceeds twelve (12) months, Premier reserves the right on each anniversary of the Effective Date of each Work Order to increase its fees for Services by reference to the Mercer’s wage inflation report published by Mercer and shared with Client, if the average salary increase for the United States exceeded [\*\*\*] for the preceding calendar year. The survey information will be used to calculate a reasonable inflation factor relevant to the Budget for Services to reflect the changes in the salaries paid to its employees and other cost increases. An estimate of the increase will be included in each affected Work Order, and the actual increase shall be applied to all invoices and subsequent payments, beginning on the first anniversary of the Effective Date of the affected Work Order.

### **3.8 Regulatory and Investigative Fees**

Client will reimburse Premier for any fees imposed by a regulatory or investigative authority which are imposed as a result of Premier's engagement by Client and which are not included in the Budget for Services. Hourly costs of Premier's staff time in handling such regulatory or investigative fees or inquiries will be charged at Premier's then current hourly rates. Such fees and costs may include, without limitation:

- a. any fee or charge imposed by the FDA pursuant to 21 CFR §20.45;
- b. Generic Drug User Fees (imposed by the Generic Drug User Fee Amendments of 2012); or Premarket Approvals ("PMAs"), Product Development Protocols ("PDPs"), Biologics Licensing Applications (BLAs for certain medical devices reviewed by FDA's Center for Biologics Evaluation and Research), certain supplements, and Premarket Notification 510(k)s (authorized by the October 26, 2002 the Medical Device User Fee and Modernization Act of 2002);
- c. any fees imposed by the Prescription Drug User Fee Act ("PDUFA");
- d. costs of responding to inquiries by the Centers for Medicare and Medicaid Services ("CMS") pertaining to the Physicians Payment Sunshine Act reporting; and
- e. the costs of Premier's staff time and any expenses, including legal fees, incurred by Premier in responding to an investigation by the US Federal Trade Commission ("FTC"), Securities and Exchange Commission ("SEC"), Financial Industry Regulatory Authority ("FINRA") or any other regulatory or investigative authority which requires information from Premier about or pertaining to Client's business, the Services and/or this Agreement.

### **4.0 TERM AND TERMINATION**

#### **4.1 Term**

Unless earlier terminated according to Section 4.2, 4.3, 4.4 or 4.5 below, this Agreement will remain in effect for an initial term of two (2) years from the Effective Date, and thereafter will renew automatically for one (1) year terms unless either Party notifies the other Party of termination of the Agreement no later than sixty (60) days prior to renewal hereof. In the event of non-renewal by either Party, the term and conditions of this Agreement shall continue to govern any outstanding Work Order or Amendment until completion of the Services described in such Work Order, Amendment, or termination of the Work Order.

#### **4.2 Termination without Cause**

Client may terminate the Agreement or any Work Order issued hereunder for any reason upon sixty (60) days written notice to Premier, pursuant to Section 18. Should Client terminate this Agreement or a Work Order without cause, the termination process and associated fees will be as follows:

- a. Client and Premier will meet promptly but in any event within thirty (30) days of Premier's receipt of such termination notice to develop a plan for (i) closing down administration of this Agreement; or (ii) closing down the Study which is the subject of the terminated Work Order, which will include transferring any remaining tasks or other responsibilities to Client or its designee.
- b. Client will pay to Premier any unpaid fees for Services or pass-through costs incurred in connection with completed Services up through such termination notice, as well as the Services performed and the pass-through costs incurred in the course of winding down or closing out the terminated Work

Order. If a Work Order's payments are based on Milestones achieved, Client will pay for Services performed towards the completion of any Milestone which was not reached at the time of termination.

#### **4.3 Termination by Client for Cause**

Failure of Premier to comply with any of the material terms or conditions of this Agreement or any Work Order will entitle Client to give written notice of default pursuant to Section 18. If Premier does not cure the default within sixty (60) days of receipt of notice (or for such reasonable amount of time thereafter, if the default is not susceptible of cure within sixty [60] days), this Agreement may be terminated by Client. Client will pay Premier for all Services properly rendered and Pass-Through Expenses incurred up through the date of notice of default. As soon as practicable following receipt of notice of termination under this Section 4.3, Premier will submit an itemized accounting of all incurred Pass-Through Expenses and costs, costs anticipated, and payments received through the date of termination in order to determine a balance to be paid by either Party to the other. Such balance will be paid by either Party to the other Party within thirty (30) days from the date of termination. A bona fide dispute over any amounts owed the other party shall not constitute a cause for termination unless the Parties have exhausted all the remedies outlined in Paragraph 27 ("Dispute Resolution").

#### **4.4 Termination by Premier for Cause**

Failure of Client to comply with any of the material terms or conditions of this Agreement or to respond to Premier's inquiries or requests for information will entitle Premier to give written notice of default pursuant to Section 18. If Client does not cure the default within sixty (60) days of receipt of notice (or for such reasonable amount of time thereafter, if the default is not susceptible of cure within sixty [60] days), this Agreement may be terminated by Premier, which will cease performance of Services. The cessation of Services in accordance with this Section 4.4 will not be a default of performance obligations by Premier, nor will it be a breach of this Agreement or any Work Order. Client will pay to Premier all amounts due and owing for Services performed, Pass-Through Expenses incurred, costs associated with winding up activities, as well as any late fees which may be due, pursuant to Section 3.5 above.

If in the reasonable assessment of Premier, its continued performance of the Services contemplated by this Agreement or any Work Order could constitute a potential or actual violation of legal, regulatory, ethical or scientific standards, then Premier may terminate this Agreement or any Work Order by giving written notice stating the effective date (which may not be less than sixty [60] days from the notice date) of such termination. The Parties shall use all reasonable efforts to rectify the alleged violation prior to the end of the sixty (60) day notice period.

#### **4.5 Termination for Other Reasons**

Either Party may terminate this Agreement and all Work Orders hereunder, effective immediately upon written notice to the other Party, if the other Party: (i) files a voluntary petition in bankruptcy or has an involuntary bankruptcy petition filed against it, which is not dismissed within thirty (30) days after its institution; (ii) is adjudged as bankrupt; (iii) becomes insolvent; (iv) has a receiver, trustee, conservator or liquidator appointed for all or a substantial part of its assets; (v) ceases to do business; (vi) commences any dissolution, liquidation or winding up; or (vii) makes an assignment of its assets for the benefit of its creditors. To the extent permitted by law, Client will pay to Premier all amounts due and owing for Services performed, Pass-Through Expenses incurred, costs associated with winding up activities, as well as any late fees which may be due, pursuant to Section 3.5 above.

## **4.6 Survival**

Termination of this Agreement will not relieve the Parties of any obligation accruing prior to such termination. In addition, Section 3.0 (Payment), Section 4.0 (Term and Termination), Section 5.0 (Representations and Warranties), Section 6.0 (Debarment Certification), Section 9.0 (Disposition of Computer Files and Study Materials), Section 10 (Ownership of Data and Intellectual Property), Section 11 (Confidential Information), Section 13.0 (Indemnification), and Section 16.0 (Non-Solicitation) as well as any other sections which by their nature should survive, will survive termination of this Agreement indefinitely, or for the period of time noted in the specific section.

## **5.0 REPRESENTATIONS AND WARRANTIES**

### **5.1 Acknowledgments**

Client acknowledges and agrees that the results of the Services to be provided hereunder are inherently uncertain and that, accordingly, there can be no assurance, representation or warranty by Premier that the drug, compound, device or other material which is the subject of research covered by this Agreement or any Work Order issued hereunder can, either during the term of this Agreement or thereafter, will be successfully developed or, if so developed, will receive the required approval by any regulatory authority.

### **5.2 Mutual Representations**

Each of the Parties represents, warrants and covenants to the other that: (i) it is a corporation duly incorporated, validly existing and in good standing; (ii) it has taken all necessary actions on its part to authorize the execution, delivery and performance of the obligations undertaken in this Agreement, and no other corporate actions are necessary with respect thereto; (iii) it is not a party to any agreement or understanding and knows of no law or regulation as of the Effective Date that would prohibit it from entering into and performing this Agreement; (iv) when executed and delivered by it, this Agreement will constitute a legal, valid and binding obligation of it, enforceable against it in accordance with this Agreement's terms; (v) it is duly licensed, authorized or qualified to do business and is in good standing in every jurisdiction in which a license, authorization or qualification is required for it to perform its obligations under this Agreement; and (vi) it will not enter into any other agreements which would interfere or prevent performance of its obligations described herein.

### **5.3 Representations and Warranties of Client**

- a. Client represents and warrants that it has the right, title and interest in the drug, compound, device or other material which is the subject of research covered by this Agreement or any Work Order (whether such right, title and interest is held solely by Client or jointly with others), and that it has the legal right, authority and power to enter into this Agreement and to perform each Study which is the subject of a Work Order issued hereunder.
- b. Client represents, that, to the best of its knowledge, all Client materials, including without limitation, any study drug, supplied under this Agreement, and Premier's use of same as permitted under this Agreement, shall not infringe any copyright, trademark, trade secret, patent or other intellectual property right of any third party.
- c. Client represents and warrants that all necessary approvals under Applicable Law shall be obtained prior to the shipment of any products, drugs, or devices (the "Products"), and that all Products have been manufactured according to Good Manufacturing Practice ("GMP"), and any other Applicable Laws. In any event, the Products will be shipped, properly packaged and labeled, to Premier for distribution or directly to the Trial Sites by Client or its representative.

- d. If Client requires Premier to use MedDRA to code, analyze or report data for a Study, Client represents and warrants that it has a current and valid license agreement with the Maintenance and Support Services Organization (“MSSO”) to use MedDRA. Furthermore, if Premier is required to use WHO Drug, WHO Herbal or WHO ART for coding of data, Client warrants and represents that it has a current and valid license agreement with The Uppsala Monitoring Centre for the dictionaries which Premier will be required to use. If Client does not currently have such licenses, it represents and warrants that such licenses will be in place prior to the delivery of data by Premier which is coded using these dictionaries. Premier will not be liable to Client for use of data coded without proper licensing, and Client will hold Premier harmless in these occasions. In the event Client requests that Premier perform services which require Premier to distribute MedDRA terminology or WHODrug dictionary to third parties, Client shall be responsible for ensuring that all such third parties possess the necessary MedDRA and/or Uppsala Monitoring Centre product licenses.

#### **5.4 Representations and Warranties of Premier**

- a. Premier represents and warrants that the personnel assigned to perform Services rendered under this Agreement will be properly trained, qualified and capable professionally in their subject matter.
- b. Premier further represents and warrants that it will make available to Client or to the responsible regulatory authority relevant records, programs, and data as may be reasonably requested by Client for purposes related to filing and prosecution of Client's related new drug applications; provided such request is consistent with all Applicable Laws that protect confidentiality of personal data.
- c. No Conflict. Premier represents and warrants to Client that it is not a party to any agreement or under any condition which would create a conflict of interest or would prevent it from fulfilling obligations under this Agreement and that during the term of this Agreement it will not without first obtaining the written permission of Client (which permission shall not be unreasonably withheld), enter into any agreement and/or arrangement which would create a conflict of interest for it in performing any Services. A “conflict of interest” shall mean management of a study for a different client of Premier, which would compete for recruitment of subjects to be enrolled under a Protocol, including any study in the same patient population defined by Protocol eligibility criteria during the active enrollment period of the Study.

#### **5.5 No Other Warranties**

The Parties’ warranties and representations contained in this Agreement are in lieu of all other warranties expressed or implied.

#### **6.0 DEBARMENT CERTIFICATION**

- a. Premier certifies that it has not been debarred under Section 306 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §335(a) or (b) or any equivalent local law or regulation. In the event that Premier becomes debarred, Premier will notify Client immediately in writing.
- b. Premier certifies that it has not used and will not use in any capacity the services of any individual, corporation, partnership, or association which has been debarred under Section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C §335(a) or (b) or any equivalent local law or regulation. In the event that Premier becomes aware of or receives notice of the debarment of any individual,

corporation, partnership, or association providing services to Premier, which relate to the Services being provided under this Agreement, Premier will notify Client immediately in writing.

## **7.0 AUDIT AND INSPECTIONS**

### **7.1 Audit by Client**

- a. Routine Audits. During the term of this Agreement, Premier will permit representatives of Client who are not competitors of Premier to examine, at a reasonable time during normal business hours and subject to at least ten (10) business days prior written notice to Premier: (i) the facilities where the Services are being, will be or have been conducted; and (ii) related study documentation. The purpose of such audit will be to enable Client to confirm that the Services are being or will be or have been conducted in conformance with applicable standard operating procedures, a specific Work Order, this Agreement and in compliance with Applicable Laws and regulations. Client shall pay the reasonable costs of any such audits, including the costs of time spent by Premier employees in preparation and attendance at the audit. Routine audits will be limited to one per calendar year. Premier will provide copies of any materials reasonably requested by Client during such audit. Premier will, at its own costs and expense, implement all reasonable modifications that prove necessary subsequent to the findings of the audit made by or on behalf of Client.
- b. “For cause” audits. During the term of this Agreement, Client shall have the right to conduct “for cause” audits in the event of a reasonable suspicion that Premier is not performing the Services correctly or in conformity with applicable standard operating procedures, a specific Work Order, this Agreement or Applicable Laws. Client will only pay the costs of time spent by Premier employees in preparation and attendance at the audit if the audit does not result in a finding that Premier performance was materially deficient, and that corrective action is required. Premier will cooperate fully in such audit and will provide copies of any materials reasonably requested by Client during such audit.

### **7.2 Inspection by Regulatory Authorities**

During the term of this Agreement, each Party will permit regulatory authorities to examine, (i) the facilities where the Services are being conducted; (ii) study documentation; and (iii) any other relevant information, including information that may be designated by one or both of the Parties as confidential, which is reasonably necessary for Regulatory Authorities to confirm that the Services are being conducted in compliance with Applicable Laws. Each Party will immediately notify the other Party if any Regulatory Authority schedules, or without scheduling, begins an inspection that relates to the Services or to the Parties’ respective obligations hereunder.

Premier shall timely provide Client with a copy of any inspection report related to the Services pursuant to this Agreement. Client shall be responsible for all reasonable costs and expenses related to Premier’s hosting of audits by Regulatory Authorities and any other obligations set forth in this Section if not otherwise included in the Work Order or Amendment.

## **8.0 SERIOUS BREACH**

- a. “Serious Breach” is defined as a deviation from a clinical trial protocol and/or GCP which is likely to affect to a significant degree, the safety and rights of a study subject or the reliability and robustness of the data generated in the clinical trial. This includes a breach which is more than a technical deviation of the trial protocol or GCP. Serious Breaches may include (a) material deviations from the conditions and principles of GCP and/or (b) significant deviations from the protocol, which are likely to affect to a

significant degree: (i) the safety or physical or mental integrity of the Study subjects of the clinical trial; or (ii) the scientific value or integrity of the clinical trial.

- b. Premier will notify Client in writing of any Serious Breaches within forty-eight (48) hours of discovery.
- c. Upon notification from Premier of a Serious Breach Client shall:
  - i. inform Premier of its intended course of action; and
  - ii. inform the relevant IRB or regulatory authority (for example, MHRA, FDA), if appropriate and required by Applicable Laws.
- d. Client shall primarily be responsible for all notifications to all applicable regulatory authorities. However, Premier may also notify the Client in writing of any such Serious Breach if, in its opinion, such reporting is required by regulation or ethical obligation (regardless of whether or not the Client has chosen to inform the regulatory authorities).

## **9.0 DISPOSITION OF COMPUTER FILES AND STUDY MATERIALS**

Premier will take reasonable and customary precautions, including periodic backup of computer files, to prevent the loss or alteration of Client's Study Data, documentation and correspondence. Upon expiration or termination of each Work Order, Premier will deliver to Client all Client Information, defined below in Section 11.1, in its possession unless Client directs otherwise. Client may communicate any special request for the disposition or storage of Study-related materials and/or data in writing to Premier, and Client will bear all costs incurred by Premier in complying with any such written requests. Premier will provide a written estimate to Client, and Client will provide written approval of all such costs prior to any action by Premier.

In the event that Client requests Premier to retain Study-related materials or Client Information on Client's behalf beyond the expiration or termination of each Work Order (hereinafter the "Archive"), reasonable costs for creating and maintaining the Archive will be included in the affected Work Order.

During the Archive term, Client remains fully responsible for the hosting and conduct of any inspection activities performed by Regulatory Authorities as described in Section 7.2. Client will immediately notify Premier if any Regulatory Authority schedules, or without scheduling, begins an inspection that relates to the Archive. Premier will facilitate access to the Archive for inspection purposes as instructed by Client. Client may request Premier to provide hosting and conducting of any inspection activities during the Archive term, if agreed to in writing by both Parties. Client remains responsible for all reasonable costs and expenses related to Premier's hosting of inspection activities by Regulatory Authorities during the Archive term.

Notwithstanding anything to the contrary in the preceding paragraph, Premier shall be entitled to retain in confidence (i) one (1) business copy of Client Information and all materials created by Premier containing Client Information, including, without limitation, notes and memoranda, solely for the purpose of administering Premier's obligations under this Agreement; and (ii) Client Information contained in Premier's electronic backup files that are created in the normal course of business pursuant to Premier's standard protocol for preserving its electronic records. All such records will be subject to the terms of Section 11 below, on Confidentiality.

## **10.0 OWNERSHIP OF DATA AND INTELLECTUAL PROPERTY**

All data (including, without limitation, written, printed, graphic, video and audio material, and information contained in any computer database or computer readable form) generated by Premier in the course of conducting the Services or related to the Services or Client Information (hereinafter the "Data") will be Client's sole and exclusive property worldwide. Any copyrightable work created in connection with performance of the Services

and contained in the Data will be considered work made for hire, whether published or unpublished, and all rights therein will be the property of Client as employer, author and owner of copyright in such work.

[\*\*\*]

## 11.0 CONFIDENTIAL INFORMATION

### 11.1 Client Confidential Information

- a. Client may disclose confidential information to Premier during the course of this Agreement. All information provided by or on behalf of Client, and all data collected by Premier during the performance of the Services are deemed to be the confidential information of Client (hereinafter referred to as "Client Information"). Premier will not disclose Client Information to any person other than its Affiliates and its and their employees, agents, independent contractors, Investigators, Trial Sites and Subcontractors who reasonably need to know such Client Information for performance of the Services, and Premier and its Affiliates and their respective employees, agents, Investigators, Trial Sites, Subcontractors and independent contractors involved in the Services or use any such information for any purpose other than the performance of Services without the prior written consent of Client, except that Premier may share Client Information with Client's Affiliates, if requested by Client.
- b. Premier will ensure that its and its Affiliates' employees, agents, Subcontractors and independent contractors involved in the performance of the Services will comply with terms substantively similar to the confidentiality and non-use provisions of this Agreement. Contracts with Trial Sites will include confidentiality provisions no less restrictive than these terms herein. Premier will disclose Client Information only to those of Premier's or Client's Affiliates, and their respective employees, agents, Subcontractors, Investigators, Trial Sites and independent contractors who reasonably need to know Client Information for the purposes of carrying out a Work Order.
- c. Premier will exercise due care to prevent the unauthorized disclosure and use of Client Information.
- d. This confidentiality, nondisclosure and nonuse provision will not apply to Client Information that Premier can demonstrate by competent evidence:
  - i. was known by Premier before the Effective Date or which is independently discovered, after the Effective Date, without the aid, application or use of Client Information, as evidenced by dated written records;
  - ii. was in the public domain at the time of receipt of Client Information or subsequently became publicly available through no omission or action of Premier or its Affiliates or their respective employees, agents, Investigators, Trial Sites, Subcontractors or independent contractors; or
  - iii. was disclosed to Premier on a non-confidential basis by a third party authorized to disclose it.
- e. In no event will either Party be prohibited from disclosing confidential information of the other Party to the extent required by law to be disclosed, provided that the disclosing Party provides the non-disclosing Party with written notice thereof, prior to disclosure, to the extent reasonably practicable, discloses only what is required to be disclosed by law or regulation, and, at the non-disclosing Party's request and expense, cooperates with the non-disclosing Party's efforts to obtain a protective order or other confidential treatment of the confidential information required to be disclosed.



## 11.2 Premier Confidential Information

Client acknowledges and agrees that business processes, contract terms, prices, procedures, policies, methodologies, systems, computer programs, software, applications, databases, proposals and other documentation generally used by Premier and not developed or modified solely for Client are the exclusive proprietary and confidential property of Premier (hereinafter "Premier Information"). Client agrees that all Premier Information, along with any improvement, alteration or enhancement made thereto during the course of the performance of the Services, will be the exclusive proprietary and confidential property of Premier, and will be subject to the same degree of protection by Client as is required of Premier to protect Client Information.

## 12.0 DATA PROTECTION

The Parties shall undertake to comply with all applicable regulations on Personal Data processing ("**Data Privacy Laws**"), including but not limited to; orders and authorizations of any Data Protection Authority, the national and international legislation on clinical trials, and the specific provisions applicable to studies, the Standards for Privacy of Individually Identifiable Health Information ("**Privacy Rule**") under the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"), and the Regulation (EU) 2016/679 (hereinafter referred to as the "**GDPR**").

Capitalized terms used in this section have the meaning set forth below or otherwise defined in this Agreement:

"**Data Controller**" in this case, refers to Client and its authorized persons, which determine the purposes and means of processing of Personal Data.

"**Data Processor**" means Premier or any other entity that processes Personal Data on behalf of the Data Controller and under its control.

"**Data Protection Authority**" means the relevant data protection supervisory authority in each country that the Services take place in.

"**Member State**" means any relevant member state of the European Union ("**EU**") or European Economic Area ("**EEA**") from time to time.

"**Model Clauses**" means the Standard Clauses for the Transfer of Personal Data to Processors in Third Countries under the Directive approved by Commission Decision of February 5, 2010, including Appendices 1 and 2 thereto.

"**Personal Data**" means any information relating to an identified or identifiable natural person; an identifiable or identifiable natural person (a "**Data Subject**") is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his/her physical, physiological, mental, economic, cultural or social identity.

"**Personal Data Breach**" means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, personal data transmitted, stored or otherwise processed

"**Subprocessor**" means any third party (other than Premier's employees), appointed in accordance with this Agreement, that processes Personal Data on behalf of Premier in order to provide the Services.

**“Transfer”, “Transferred” or “Transferring”** means, whether by physical or electronic means, across national borders, both (a) the moving of Personal Data from one location or person to another, and (b) the granting of access to Personal Data by one location or person to another.

Premier will (and ensure that any Subprocessor acting under Premier’s authority will):

- (a) Process the Personal Data only (i) as needed to provide the Services, (ii) in accordance with the specific documented instructions Premier has received from Client, including with regard to any Transfers, as set forth in this Agreement or any related Project Agreements/Work Orders, unless required otherwise to comply with any applicable or Member State law (in which case, Premier shall provide prior notice to Client of such legal requirement, unless that law prohibits this disclosure on important grounds of public interest);
- (b) Ensure that persons authorized to Process the Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality;
- (c) Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, Premier shall implement appropriate technical and organizational security measures to ensure a level of security appropriate to the risk;
- (d) Assist Client by appropriate technical and organizational measures, insofar as this is possible, for the fulfilment of Client’s obligation to respond to requests for exercising Data Subjects’ rights to access, correct, delete, restrict processing of, port, or be informed about the processing of their Personal Data, taking into account the nature of the processing;
- (e) At Client’s discretion, anonymize, delete or return all the Personal Data to Client after the end of the provision of Services relating to processing, and delete existing copies unless applicable or Member State laws require Premier to store the Personal Data;
- (f) Maintain all records and provide Client with all information necessary to demonstrate compliance with the obligations laid down in Data Privacy Laws, and allow for and contribute to audits, including inspections, conducted by Client or another auditor mandated by Client, at Client’s expense, provided that Client provides at least 10 business days’ written notice to Premier of an intention to conduct such audit;
- (g) Assist the Data Controller with meeting the other obligations that may be incumbent on the Data Controller according to Data Privacy Laws where the assistance of the Data Processor is implied and where the assistance of the Data Processor is necessary for the Data Controller to comply with its obligations. This includes but is not limited to, at the request to provide the Data Controller with all necessary information about an incident under (k), and all necessary information for an data protection impact assessment;
- (h) Promptly inform Client if, in Premier’s opinion, an instruction infringes Data Privacy Law provisions;
- (i) Not Transfer any Personal Data outside its country of origin (and shall not permit our approved Subprocessors to Transfer any such Personal Data) without the prior consent

of Client. Premier will, where Transferring Personal Data originating from the EEA, enter into the Model Clauses with Client governing such Transfer, attached to and executed in this Agreement as Exhibit C, unless another adequacy mechanism for the Transfer exists as stipulated in GDPR Chapter V. For all other Transfers, Premier will act under the instructions of the Data Controller to ensure that all such Transfers of Personal Data are performed in compliance with Data Privacy Laws, which may include obtaining the consent of the Data Subject for the Transfer, or obtaining authorization from a Data Protection Authority;

- (j) Not share any Personal Data with or engage any Subprocessor without prior specific or general written authorization of Client. Where such general authorization has been given, Premier will promptly inform Client of any intended changes concerning the addition or replacement of Subprocessors. In addition, Premier will impose data protection obligations on any Subprocessor that are at least as strong as those in this Agreement. Where the Subprocessor fails to fulfil its data protection obligations, Premier shall remain fully liable to Client for the performance of the Subprocessor's obligations; and
- (k) Promptly and thoroughly investigate all Personal Data Breaches. Premier will notify Client without undue delay in the event of any known or suspected Personal Data Breach. In addition to any method of notice described in the Agreements, notice of any Personal Data Breach shall also be reported to Client at:

Telephone: [\*\*\*]

Email: [\*\*\*]

Premier shall take all necessary steps to eliminate or contain the exposure of Personal Data, and keep Client informed of the status of the Personal Data Breach and all related matters. Premier further agree to provide reasonable assistance and cooperation requested by Client and/or Client's designated representatives, in the furtherance of any notification to a Data Protection Authority, correction or remediation of any Personal Data Breach and/or the mitigation of any potential damage.

### **13.0 PUBLICITY**

Client may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of Premier consistent with applicable international copyright laws; provided such use does not constitute an endorsement of any commercial product or service by Premier. Neither Party will disclose publicly or utilize in any advertising or promotional materials or media the existence of this Agreement or its association with the other Party except for disclosure to the Party's Affiliates, or use of the other Party's name or the name of any of the other Party's Affiliates, divisions, subsidiaries, products or investigations without the prior written permission of the other Party; provided, however, that Premier may use the name of Client in its list of customers and may use Client's logo or trademarks on proposals and presentation specifically prepared for Client. Premier may use case studies based on the Services in its marketing or promotional materials; provided that such materials make no mention of Client or Client's products which were the subject of the Services. Further, either Party may make such public disclosures as it determines, based on advice of counsel, and are reasonably necessary to comply with laws or regulations.

### **14.0 INDEMNIFICATION**

#### **14.1 Client's Agreement**

- a. Client will indemnify, defend and hold harmless Premier, its Affiliates, and their officers, directors, agents, employees, and independent contractors approved by Client (each a “Premier Indemnitee”) against any claim, suit, action, proceeding, arbitration or investigation, pending or threatened by a third party (each a “Claim”) against a Premier Indemnitee based on, relating to or in connection with the Services, including, but not limited to, court costs, reasonable legal fees, awards or settlements. Premier will promptly notify Client upon receipt of notice of any Claim for which it intends to seek indemnification hereunder; provided that the failure to give such notice will not relieve Client of its obligations under this Section except to the extent, if at all, it is prejudiced thereby. Premier will permit Client's attorneys and personnel, at Client's discretion and cost, to handle and control the defense of any such Claim. In the event that representation of Premier and Client by the same counsel is a conflict of interest for such counsel, Premier may select its own independent counsel, at Premier’s expense, without relieving Client of its obligations under this Section 14.1.
- b. Under no circumstances, however, will Client accept liability, settle or otherwise compromise any Claims subject to indemnification under this Section without prior written consent of Premier, which consent shall not be unreasonably withheld, conditioned or delayed. Premier will fully cooperate and aid in any such defense.
- c. Client does not agree, and will have no obligation to indemnify, defend, or hold harmless Premier against any Claim to the extent that such Claim arose as a result of Premier’s negligence, recklessness, intentional misconduct or material breach of this Agreement or any Work Order hereunder. Under such circumstances Premier will repay to Client all reasonable defense costs incurred by Client on its behalf.

## **14.2 Premier’s Agreement**

- a. Premier will indemnify, defend and hold harmless Client, and its employees, officers, and directors against any and all Claims including, but not limited to, reasonable court costs, legal fees, awards or settlements based on or resulting from Premier’s negligence, intentional misconduct, or material breach of this Agreement or any Work Order issued hereunder. Client will promptly notify, in writing, Premier upon receipt of notice of any Claim for which it intends to seek indemnification hereunder; provided that the failure to give such notice will not relieve Premier of its obligations under this Section except to the extent, if at all, it is prejudiced thereby. Client will permit Premier’s attorneys and personnel, at Premier’s discretion and cost, to handle and control the defense of any such Claim. In the event that representation of Client and Premier by the same counsel is a conflict of interest for such counsel, Client may select its own independent counsel, at Client’s expense, without relieving Premier of its obligations under this Section.
- b. Under no circumstances, however, will Premier accept liability, settle or otherwise compromise any claims subject to indemnification under this Section without prior written consent of Client, which consent shall not be unreasonably withheld, conditioned or delayed. Client will fully cooperate and aid in any such defense.
- c. Premier does not agree, and will have no obligation to indemnify, defend or hold harmless Client against any claim to the extent that such claim arose as a result of Client’s negligence, recklessness, intentional misconduct or material breach of this Agreement or any Work Order hereunder. Under such circumstances Client will repay to Premier all reasonable defense costs incurred by Premier on its behalf.

### **14.3 Limits of Liability**

Premier's liability for direct damages hereunder will not exceed the total fees payable by Client to Premier under the applicable Work Order. In no event will Premier be liable to Client for any indirect, incidental, special, or consequential damages or lost profits arising out of or related to its provision of Services to Client, even if Premier has been advised of the possibility of such damages, except to the extent that such damages result from the gross negligence, recklessness or intentional misconduct of Premier, its employees, independent contractors or agents.

Notwithstanding anything to the contrary in this Agreement or in any Work Order, the Parties agree that Premier shall not be liable for: (i) the lack of efficacy or complications associated with any Study Drug outside of Premier's control; or (ii) the act of any principal investigator, sub-investigator, Study coordinator, nurse, nurse-practitioner, pharmacist, or any other employee or consultant licensed to practice medicine or employed by or under agreement with any hospital, clinic, nursing service, site management organization, or other entity which is contracted to be a Trial Site for any study conducted pursuant to this Agreement, even if Premier shall pay, compensate, select, train, contract with or otherwise interact with any of the foregoing.

### **15.0 INSURANCE**

#### **15.1 Client Insurance**

During the term of this Agreement, and for a period of three (3) years following the termination of this Agreement, Client shall maintain in full force and effect a policy or policies or self-insurance of:

- a. [\*\*\*]
- b. [\*\*\*]
- c. clinical trials insurance in compliance with local compulsory requirements. Client will extend this coverage to protect Premier from and against any action or actions for property damage, personal injury or death arising from activities properly undertaken, or undertaken at the express instructions of Client, within the terms of the Agreement.

Premier may from time to time request in writing evidence confirming such insurance.

#### **15.2 Premier Insurance**

Premier shall at all times during the term of this Agreement, and for a period of three (3) years following the termination of this Agreement, provide and maintain at its own expense, the following types of insurance:

- a. [\*\*\*]
- b. [\*\*\*]

#### **15.3 General Terms**

- a. All policies shall be issued by one or more insurance companies rated A- VII or better by the BEST Rating guide or its equivalent.
- b. Such insurance may be provided on a claims-made basis (with the exception of workers compensation and employers' liability); however, such insurance shall have a retroactive date prior to the date that

any work will be performed pursuant to the Agreement, and shall be maintained (or shall have an extended reporting period) of at least three (3) years after the termination of this Agreement.

- c. In the event that such policies are cancelled, terminated or altered, the insured Party shall endeavor to provide at least thirty (30) days prior written notice to the other Party.
- d. It is agreed and understood that the above limits are minimum required amounts and are not limitations of liability.

## **16.0 INDEPENDENT CONTRACTOR RELATIONSHIP**

Premier and Client are independent contractors. Nothing in this Agreement will be construed to create the relationship of partners, joint venturers, or employer and employee between Premier and Client or Premier's employees. Neither Party, nor its employees, or independent contractors will have authority to act on behalf of or bind the other Party in any manner whatsoever unless otherwise authorized in this Agreement or a specific Work Order or in a separate writing signed by both Parties.

## **17.0 NON-SOLICITATION**

Neither Party, during the term of this Agreement and for twelve months thereafter, will, without the prior written consent of the other Party, directly or indirectly solicit for employment or contract, attempt to employ or contract with or assist any other entity in employing, contracting with or soliciting for employment or contract any employee or executive who is at that time employed/contracted by the other Party and who had been employed/contracted by the other Party in connection with one or more Work Orders issued hereunder. Provided, however, that the foregoing provision will not prevent either Party from conducting solicitation via a general advertisement for employment that is not specifically directed to any such employee or from employing any such person who responds to such solicitation.

## **18.0 NOTICES**

Except as otherwise provided, all communications and notices required under this Agreement will be mailed or sent via nationally recognized overnight courier to the addresses set forth below, or to such other addresses as the Parties from time to time specify in writing.

If to Premier:

Premier Research International LLC  
3800 Paramount Parkway, Suite 400  
Morrisville, NC 27560-6949  
Attention: Chief Commercial Officer  
Copy to: Senior Vice President, Legal Affairs

If to Client:

Cassava Sciences, Inc.  
7801 N. Capital of Texas Hwy.  
Suite 260  
Austin, TX 78731  
[\*\*\*]

## **19.0 FORCE MAJEURE**

If the performance of this Agreement by Premier or Client is prevented, restricted, interfered with or delayed (either totally or in part) by reason of any cause beyond the control of the Parties (including, but not limited to, acts of God, flood, sabotage, explosion, epidemic, pandemic, weather, war, insurrection, terrorism, cyberattacks, civil strike, governmental laws and regulations imposed after the fact, power failures, riots or extensive power failure), the Party so affected will, upon giving notice to the other Party as soon as is practical, be excused from such performance to the extent of such prevention, restriction, interference or delay; provided that the affected Party will use reasonable efforts to avoid or remove such causes of non-performance and will continue

performance whenever such causes are removed. In the event such failure continues for a period of sixty (60) days or more, either Premier or Client may terminate the applicable Work Order by giving written notice thereof to the other Party.

## **20.0 GOVERNING LAW**

This Agreement will be governed in all respects by the laws of the State of Delaware, United States of America without regard to its conflict of laws principles.

## **21.0 SEVERABILITY**

If any of the provisions or a portion of any provision of this Agreement is held to be unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the enforceable portion of any such provision and/or the remaining provisions will not be affected thereby.

## **22.0 ASSIGNMENT**

Neither Party may assign this Agreement without the prior written consent of the other Party, which consent will not be unreasonably withheld; provided, however, that either Party may assign this Agreement without consent to a successor in interest to substantially all of the business of that Party to which the subject matter of this Agreement relates upon delivery to the other Party of notice of such assignment.

## **23.0 WAIVER**

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances will be deemed to be construed as a further or continuing waiver of such term, provision or condition or of any other term, provision or condition of this Agreement.

## **24.0 ENTIRE AGREEMENT**

This Agreement, including all Exhibits, Work Orders, and associated Amendments hereto contains the full understanding of the Parties with respect to the Services and supersedes all existing Agreements, and all other oral, written or other communications between the Parties concerning the subject matter hereof except for the Mutual NonDisclosure Agreement with an effective date of March 22, 2021 made by and between Cassava Sciences, Inc. and Premier Research International LLC. This prior Mutual Confidentiality Agreement shall only apply to exchanges of confidential information prior to the execution of this Agreement. This Agreement will not be modified in any way except in writing and signed by a duly authorized representative of Client and an authorized officer of Premier.

## **25.0 ENGLISH LANGUAGE**

The Parties hereto confirm that this Agreement as well as any other documents relating hereto, including notices, have been and shall be drawn up in the English language.

## **26.0 COUNTERPARTS**

This Agreement may be executed in several counterparts, each of which will be deemed an original but all of which will constitute one and the same instrument. To the extent that counterparts are in a language other than English, the English language version shall control.

## **27.0 DISPUTE RESOLUTION**

In the event a dispute, claim or controversy relating to this Agreement or any Work Order arises between the Parties, the disputing party shall provide the other party with a written notice of the nature of the dispute, including sufficient detail to allow the other party to evaluate the dispute and negotiate its resolution. The Parties will use all reasonable efforts to amicably resolve the dispute through direct discussions for a period of thirty (30) business days from initial notice of such dispute. The senior management of each Party is committed to respond to any such dispute.

If for any reasons such senior managers do not resolve the matter, then the parties agree to refer the dispute to the CEO of each party. The CEOs shall meet in person or by telephone (including video conferencing) to amicably resolve the dispute in good faith within thirty (30) business days after the matter is referred to them.

If for any reason the CEOs do not resolve the dispute then the parties shall attempt in good faith to settle the dispute through mediation conducted by a mediator to be mutually selected by the parties. Mediation will be with one (1) mediator in accordance with the Mediation Procedure established by the International Institute for Conflict Prevention and Resolution, as such procedure may be modified by mutual written agreement of the parties. Each party shall pay for its own costs and the parties shall share the costs of the mediation, including the fee of the mediator, equally. Each party agrees to continue to perform its obligations hereunder in good faith during the pendency of the mediation. All communications, both written and oral, will be as confidential.

In the event of a breach by either Party of the terms of this Agreement, the other Party shall be entitled, if it shall so elect, to institute legal proceedings to obtain damages for any such breach, or to enforce the specific performance of this Agreement and to enjoin the breaching Party from any further violation of this Agreement and to exercise such remedies cumulatively or in conjunction with all other rights and remedies provided by law.

## 28.0 AMBIGUITIES

Each Party has participated fully in the review and revision of this Agreement. Any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not apply in interpreting this Agreement. The language in this Agreement shall be interpreted as to its fair meaning and not strictly for or against any Party.

**IN WITNESS WHEREOF**, the Parties have executed this Agreement effective as of the day and year first written above.

Premier Research International LLC

Cassava Sciences, Inc.

Name: Sean Russell

Name: Remi Barbier

Title: Chief Commercial Officer

Title: President & CEO

Date: June 14, 2021

Date: June 11, 2021

Authorized Signature:

Authorized Signature:

/s/ Sean Russell

/s/ Remi Barbier



## LIST OF EXHIBITS

|            |   |
|------------|---|
| Exhibit A: | Form of Work Order  |
| Exhibit B: | Form of Amendment   |
| Exhibit C: | Data Processor Agreement<br>(Standard Contractual Clauses 2010/87/EC) |
| Exhibit D: | Volume Rebate and Non-Competitive Award Discounts                     |
| Exhibit E: | Client Signatory Authorization  |

**EXHIBIT A:**

**FORM OF WORK ORDER**

**Work Order Number:** \_\_\_\_\_

**Client Project Number:** \_\_\_\_\_

This Work Order #\_\_\_ (“Work Order”) is made and entered into on <Month> <Day>, <Year>, (the “Effective Date”), by and between <Client>, a corporation of \_\_\_\_\_ with offices at <Location> (“Client”) and **Premier Research** \_\_\_\_\_, with offices at \_\_\_\_\_ (“Premier”).

**WHEREAS**, Client and Premier have entered into that certain Master Services Agreement for dated the <day> of <month>, 201\_ (the “Agreement”);

**WHEREAS**, pursuant to the Agreement, Premier has agreed to perform certain Services in accordance with Work Orders from time to time entered into by the Parties, as more fully provided in Section 2 of the Agreement, and Client and Premier now desire to enter into such a Work Order; and

**WHEREAS**, Premier and Client desire that Premier provide certain Services pertaining to \_\_\_\_\_, (the “Study”) for the study of the drug <device> \_\_\_\_\_ (“Study Drug”) as set out in the Protocol titled: \_\_\_\_\_, which is incorporated herein by reference.

**NOW, THEREFORE**, in consideration of the mutual covenants contained herein, the Parties hereby agree as follows:

1. **Project Specifications.** Premier will perform the services described in the Project Specifications, attached hereto as Appendix A, in accordance with the Project Schedule, attached hereto as Appendix B and any other documents attached to this Work Order (“Services”).

2. **Compensation.** For performance of the Services, Client will pay to Premier the amounts described in the Budget for Services and Pass-Through Budget set forth in Appendix C, which amounts will be payable pursuant to the Payment Schedule set forth in Appendix D. Ad hoc consulting services, provided by Premier’s medical, regulatory or experts will be charged on a time and materials basis, unless such services are included in the Budget for Services.

2.1. A payment plan inclusive of an initial payment element of the total Budget for Services estimate, inclusive of Pass-Through Expenses is included in the Payment Schedule. The initial payment for Pass-Through Expenses is considered as an advance payment and shall be taken into account with the final payment(s) upon completion of the Services. **<Insert Client VAT number in Payment Schedule in Appendix D, if applicable>**

2.2. Initial payment invoices are due immediately upon execution of this Work Order. All payments are to be made in accordance with the Agreement and due within thirty (30) days of invoice date.

3. Subcontractors.  
(a) **Client-Selected Subcontractors.** Client request Premier to use the following Client –Selected Subcontractors as provided in Section 2.4 (a) of the Agreement to be used during this Study:

| Subcontractor Type | Name of Subcontractor |
|--------------------|-----------------------|
|                    |                       |
|                    |                       |

(b) Premier-Selected Subcontractors. Premier shall use the following Subcontractors as provided in Section 2.4 (c) of the Agreement during this Study:

| Subcontractor Type | Name of Subcontractor |
|--------------------|-----------------------|
|                    |                       |
|                    |                       |

4. Personal Data. Premier is authorized to process, in accordance with the Agreement and on behalf of the Client, the necessary Personal Data for providing the Services. The Personal Data to be processed pursuant to this work order is as described in the table below:

| Data categories   | Type of Data Subjects  |   |
|---|--|---|
|   | Professional contacts e.g. Investigators, site staff, Client personnel | Trial subjects e.g. patients  |
| Identification data<br>(e.g. name, surname, date of birth, initials)  | Yes  | Yes (limited*) / No   |
| Government issued identification<br>(e.g. medical records number, social security number, passport)   | Yes / No   | Yes (limited to travel arrangement purposes) / No   |
| Contact data<br>(e.g. address, phone, e-mail etc.)  | Yes (professional)   | Yes (limited to travel arrangements purposes) / Yes (limited to cell phone SMS for medication reminders) / No |
| Technical data<br>(e.g. IP address, event logs)   | Yes  | No  |
| Professional data<br>(e.g. qualification & training, including in a form of curriculum vitae(s))  | Yes  | No  |
| Business related data<br>(e.g. performance and evaluation data, opinions about individual team members)   | Yes / No   | No  |
| Economic and financial data<br>(e.g. accounting details and sunshine/transfer of value details)   | Yes  | No, except for health economics research if part of the Study   |
| Legal data<br>(e.g. any suspicion of fraud or bribery)  | Yes  | No  |
| Data conveying information about personal life<br>(e.g. relationship status and next of kin/legal guardian, quality of life questionnaires, potentially including questions about sex life, leisure activities, highest qualification held, etc.) | No   | Yes / No  |
| Demographic data<br>(e.g. gender, socio-economic class)   | No   | Yes / No  |
| Data conveying information about origins<br>(e.g. race, ethnicity etc.)   | No   | Yes (where permitted) / No  |
| Health data<br>(e.g. disease, treatments, health images etc.)   | No   | Yes   |
| Biometric data<br>(e.g. measurements, photographs allowing facial recognition, fingerprints, retinal scans)   | No   | Yes / No  |
| Genetic data<br>(e.g. somatic or germ line mutations etc.)  | No   | Yes / No  |
| Data about children<br>(e.g. where the trial subject is a pediatric patient)  | No   | Yes / No  |

\*Collection of identification data related to patients and other research participants is limited according to national law. In some countries the date of birth and initials are collected, but in other countries only the year of birth may be collected. Information will only be collected in accordance with national laws, therefore there may be variance in scope of personal data collected. In all cases, access to fully identifiable information is possible only by the authorized on-site staff and monitors only for the source data verification.

The nature of operations carried out on the Personal Data is processing related to the provision of the Services including, but not limited to; collection, analysis, storage, transfer to data centers in the United States, onward transfer to Client and regulatory bodies, aggregation for purposes of publishing study results, archiving and destruction at the end of the retention period required by law and Client.

The purpose of the processing is to provide Services in connection with facilitating the Study.

The categories of data subjects are clinical trial subjects, prospective site personnel (investigators, coordinators, nurses etc.), site personnel, clinical trial subject relatives (career, legal guardian, emergency contacts), employees of Client, Vendors, other research partners, and Subcontractors.

Name and Contact Details of Client Data Protection Officer (or equivalent):

<name>  
<Address>  
<Phone>  
<E-mail>

Name and Contact Details of Client Data Protection Representative (if applicable):

<name>  
<Address>  
<Phone>  
<E-mail>

Client has issued the following instructions for data retention:

*(Pick one)*

- Option 1:** Premier shall deliver the official copy of Client Information to Client at the end of the Services and will keep a business copy in archive, subject to Section 11 (Confidentiality) of the Agreement.
- Option 2:** Premier shall deliver the official copy of Client Information to Client at the end of the Services and will delete our copy 90 days after confirmation of delivery, at the Client's cost, as agreed upon in this Work Order. (Please note we will not be able to respond to any future queries etc.)
- Option 3:** Premier shall deliver a copy of Client Information to Client at the end of the Services and will continue to provide ongoing hosting services in the Archive for the official copy of Client Information, at the Client's cost, as agreed upon in this Work Order.

Any other specific instructions relating to data processing: \_\_\_\_\_

5. Designated Contact Person. The Premier Project Manager <or other designation for this project> who will oversee the Services in accordance with the Agreement is:

<name>  
< title>  
<Address>  
<Phone>  
<E-mail>

6. Term and Termination. The term of this Work Order will commence upon its execution by Premier and Client, and will continue until completion of the Services described in Appendix A; provided, however, that either Party may terminate this Work Order in accordance with Section 4 (Term and Termination) of the Agreement.

7. Incorporation by Reference; Conflict. The provisions of the Agreement are hereby expressly incorporated by reference into and made a part of this Work Order. In the event of a conflict between the terms and conditions of this Work Order and those of the Agreement, the terms of the Agreement will take precedence and control; provided however, in event of conflicts between the Work Order and Section 3.0 (Payment) and Section 4.0 (Term and Termination) of the Agreement, the Work Order shall control.

**IN WITNESS WHEREOF**, the Parties have executed this Work Order effective as of the day and year first written above.

**Premier Research** \_\_\_\_\_  
Authorized Signature:

<**Client**>  
Authorized Signature:

**FORM ONLY – DO NOT SIGN**

Name  
\_\_\_\_\_

Title:  
\_\_\_\_\_

Date:  
\_\_\_\_\_

**FORM ONLY – DO NOT SIGN**

Name:  
\_\_\_\_\_

Title:  
\_\_\_\_\_

Date:  
\_\_\_\_\_

**List of Appendices**

- |             |   |
|-------------|---|
| Appendix A: | Project Specifications                      |
| Appendix B: | Project Schedule                            |
| Appendix C: | Budget for Services and Pass-Through Budget |
| Appendix D: | Payment Schedule                            |
| Appendix E: | Client Signatory Authorization              |

**EXHIBIT B**

**FORM OF AMENDMENT**

**AMENDMENT #**

**Work Order No, Protocol #**

**THIS AMENDMENT #** (“Amendment #”), dated <Month> <Day>, <Year> (the “Effective Date”), is by and between <Client>, a corporation of \_\_\_\_\_ with offices at <Location> (“Client”) and **Premier Research** \_\_\_\_\_, together with its Affiliates, with offices at \_\_\_\_\_ (“Premier”).

**WHEREAS**, under the terms of a certain Master Services Agreement (the “Agreement”), dated the \_\_\_ day of \_\_\_\_\_, 201\_ by and between the Parties, Client agreed to retain Premier, and Premier agreed to be retained by Client, to perform the Services as more particularly described in the Agreement pursuant to the terms of Work Orders to be issued from time to time;

**WHEREAS**, the Parties have entered into Work Order No. \_ pursuant to the terms of the Agreement (“Work Order”); and

**WHEREAS**, the Parties hereto have entered into certain additional agreements with respect to modification of the Work Order, and they desire to memorialize such modification in this Amendment #\_.

**NOW, THEREFORE**, in consideration of the premises and of the following mutual promises, covenants and conditions hereinafter set forth, the Parties hereto agree as follows:

1. **Project Specifications**. The Services to be provided by Premier pursuant to the Work Order are hereby amended by inclusion of the Services described in Amendment Appendix \_\_, “Additional Project Specifications”, which is attached hereto and incorporated herein by reference.
2. **Project Schedule**. The Project Schedule, attached to the Work Order as Appendix \_\_, is hereby stricken and replaced by the Amended Project Schedule, attached hereto as Amendment Appendix \_\_, “Amended Project Schedule”, which is incorporated herein by reference.
3. **Budget and Payment Schedule**. Therefore, the following changes to the Work Order are hereby made:
  - a. The Budget for Services, attached to the Work Order as Appendix \_\_, is hereby stricken and replaced by the “Amended Budget”, attached hereto as Amendment Appendix \_\_, which is incorporated herein by reference.
  - b. The Payment Schedule, attached to the Work Order as Appendix \_\_, is hereby stricken and replaced by the “Amended Payment Schedule”, attached hereto as Amendment Appendix \_\_, which is incorporated herein by reference.
4. **Designated Contact Person**. The Designated Contact Person assigned to this Study has changed. Therefore, the name of the Designated Contact Person is hereby stricken and replaced by <name, title, contact>.
5. **Ratification of Balance of Agreement**. In all other respects, the terms of the Work Order are hereby ratified and affirmed by each of the Parties hereto.

6. Headings. The headings in this Amendment #\_\_ are for convenience of reference only and will not affect its interpretation.

**IN WITNESS WHEREOF**, the Parties have executed this Amendment #\_\_ effective as of the day and year first written above.

**Premier Research** \_\_\_\_\_  
Authorized Signature:

<Client>  
Authorized Signature:

**FORM ONLY – DO NOT SIGN**

**FORM ONLY – DO NOT SIGN**

Name  
\_\_\_\_\_

Name:  
\_\_\_\_\_

Title:  
\_\_\_\_\_

Title:  
\_\_\_\_\_

Date:  
\_\_\_\_\_

Date:  
\_\_\_\_\_

**List of Appendices:**

- Amendment Appendix A: Additional Project Specifications
- Amendment Appendix B: Amended Project Schedule
- Amendment Appendix C: Amended Budget
- Amendment Appendix D: Amended Payment Schedule

**EXHIBIT C:  
DATA PROCESSOR AGREEMENT  
(STANDARD CONTRACTUAL CLAUSES 2010/87/EC)**

For the purposes of Article 26(2) of Directive 95/46/EC for the transfer of personal data to processors established in third countries which do not ensure an adequate level of data protection, this Data Processor Agreement is between

- (i) **Cassava Sciences, Inc.**, a Delaware corporation with its principal address at 7801 N. Capital of Texas Hwy, Suite 260, Austin, TX 78731 (hereinafter “**Data Exporter**”) and
- (ii) **Premier Research Group Ltd** with its principal place of business at 250 South Oak Way, Green Park, Reading, Berkshire, RG2 6UG, United Kingdom for itself and on behalf of all of the entities listed at Appendix 3 hereto; and
- (iii) **Premier Research International LLC** a Delaware limited liability company with its principal place of business at 3800 Paramount Parkway, Suite 400, Morrisville, NC 27560-6949;

(entities in part (ii) and (iii) collectively hereinafter **“Data Importers”** or each entity individually a **“Data Importer”**);

each a “party”; together “the parties”.

WHEREAS, the parties wish to permit the transfer of Personal Data to the United States or other non-EEA countries for processing and appropriate purposes;

WHEREAS, the parties wish to ensure adequate protections for such Personal Data and address appropriate safeguards;

THE PARTIES have entered into this Data Processor Agreement (**“DP Agreement”**) with standard contractual clauses in order to adduce adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals for the transfer by the Data Exporter to the Data Importer of the Personal Data specified in Appendix 1.

**1. Definitions.** For the purposes of the clauses:

- 1.1. **“Personal Data”, “Special Categories of Data/Sensitive Data”, “Process/Processing”, “Controller”, “Processor”, “Data Subject” and “Supervisory Authority/Authority”** shall have the same meaning as in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data;
- 1.2. **“Data Exporter”** shall mean the Controller who transfers the Personal Data;
- 1.3. **“Data Importer”** shall mean the Processor who agrees to receive from the Data Exporter Personal Data intended for Processing on his behalf after the transfer in accordance with his instructions and the terms of this DP Agreement and who is not subject to a third country’s system ensuring adequate protection within the meaning of Article 25(1) of Directive 95/46/EC;
- 1.4. **“Sub-processor”** shall mean any Processor engaged by the Data Importer or by any other Sub-processor of the Data Importer who agrees to receive from the Data Importer or from any other Sub-processor of the Data Importer Personal Data exclusively intended for Processing activities to be carried out on behalf of the Data Exporter after the transfer in accordance with his instructions, the terms of this DP Agreement and the terms of the written subcontract;
- 1.5. **“Applicable Data Protection Law”** shall mean the legislation protecting the fundamental rights and freedoms of individuals and, in particular, their right to privacy with respect to the Processing of Personal Data applicable to a Data Controller in the Member State in which the Data Exporter is established;
- 1.6. **“Technical and Organisational Security Measures”** means those measures aimed at protecting Personal Data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, in particular where the Processing involves the transmission of data over a network, and against all other unlawful forms of Processing;
- 1.7. **“Clauses” or “Sections”** shall mean these contractual clauses, which are a free-standing document that does not incorporate commercial business terms established by the parties under separate commercial arrangements. Individual clauses may be referred to as Section.

**2. Details of the transfer.**

The details of the transfer and in particular the Special Categories of Personal Data where applicable are specified in Appendix 1 which forms an integral part of this DP Agreement.



### **3. Third Party Beneficiary Clause.**

- 3.1. The Data Subject can enforce against the Data Exporter this Section, Section 4.2 to 4.9, Section 5.1 to 5.5, and 5.7 to 5.10, Section 6.1 and 6.2, Section 7, Section 8.2, and Sections 9 to 12 as third-party beneficiary.
- 3.2. The Data Subject can enforce against the Data Importer this Section, Section 5.1 to 5.5 and 5.7, Section 6, Section 7, Section 8.2, and Sections 9 to 12, in cases where the Data Exporter has factually disappeared or has ceased to exist in law unless any successor entity has assumed the entire legal obligations of the Data Exporter by contract or by operation of law, as a result of which it takes on the rights and obligations of the Data Exporter, in which case the Data Subject can enforce them against such entity.
- 3.3. The Data Subject can enforce against the Sub-processor this Section, Section 5.1 to 5.5 and 5.7, Section 6, Section 7, Section 8.2, and Sections 9 to 12, in cases where both the Data Exporter and the Data Importer have factually disappeared or ceased to exist in law or have become insolvent, unless any successor entity has assumed the entire legal obligations of the Data Exporter by contract or by operation of law as a result of which it takes on the rights and obligations of the Data Exporter, in which case the Data Subject can enforce them against such entity. Such third-party liability of the Sub-processor shall be limited to its own Processing operations under the Clauses.
- 3.4. The parties do not object to a Data Subject being represented by an association or other body if the Data Subject so expressly wishes and if permitted by national law.

### **4. Obligations of Data Exporter.** The Data Exporter agrees and warrants:

- 4.1. that the Processing, including the transfer itself, of the Personal Data has been and will continue to be carried out in accordance with the relevant provisions of the Applicable Data Protection Law (and, where applicable, has been notified to the relevant Authorities of the Member State where the Data Exporter is established) and does not violate the relevant provisions of that Member State;
- 4.2. that it has instructed and throughout the duration of the Personal Data-Processing services will instruct the Data Importer to process the Personal Data transferred only on the Data Exporter's behalf and in accordance with the Applicable Data Protection Law and this DP Agreement;
- 4.3. that the Data Importer will provide sufficient guarantees in respect of the Technical and Organisational Security Measures specified in Appendix 2 to this DP Agreement;
- 4.4. that after assessment of the requirements of the Applicable Data Protection Law, the Technical and Organisational Security Measures are appropriate to protect Personal Data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of Processing, and that these measures ensure a level of security appropriate to the risks presented by the Processing and the nature of the data to be protected having regard to the state of the art and the cost of their implementation;
- 4.5. that the Data Exporter will ensure compliance with the Technical and Organisational Security Measures;
- 4.6. that, if the transfer involves Special Categories of Data, the Data Subject has been informed or will be informed before, or as soon as possible after, the transfer that its data could be transmitted to a third country not providing adequate protection within the meaning of Directive 95/46/EC;
- 4.7. to forward any notification received from the Data Importer or any Sub-processor pursuant to Section 5.2 and Section 8.3 to the data protection Supervisory Authority if the Data Exporter decides to continue the transfer or to lift the suspension;

- 4.8. to make available to the Data Subjects upon request a copy of this DP Agreement, with the exception of Appendix 2, and a summary description of the Technical and Organisational Security Measures, as well as a copy of any contract for sub-processing services which has to be made in accordance with this DP Agreement, unless this DP Agreement or the contract contain commercial information, in which case it may remove such commercial information;
- 4.9. that, in the event of sub-processing, the Processing activity is carried out in accordance with Section 11 by a Sub- processor providing at least the same level of protection for the Personal Data and the rights of Data Subject as the Data Importer under this DP Agreement; and
- 4.10. that the Data Exporter will ensure compliance with Section 4.1 to 4.9.

**5. Obligations of Data Importer.** The Data Importer agrees and warrants:

- 5.1. to Process the Personal Data only on behalf of the Data Exporter and in compliance with its instructions and this DP Agreement; if Data Importer cannot provide such compliance for whatever reasons, it agrees to inform promptly the Data Exporter of its inability to comply, in which case the Data Exporter is entitled to suspend the transfer of data and/or terminate this DP Agreement and any associated contract;
- 5.2. that the Data Importer has no reason to believe that the legislation applicable to it prevents it from fulfilling the instructions received from the Data Exporter and its obligations under this DP Agreement and any associated contract and that in the event of a change in this legislation which is likely to have a substantial adverse effect on the warranties and obligations provided by this DP Agreement, it will promptly notify the change to the Data Exporter as soon as it is aware, in which case the Data Exporter is entitled to suspend the transfer of data and/or terminate this DP Agreement and any associated contract;
- 5.3. that the Data Importer has implemented the Technical and Organisational Security Measures specified in Appendix 2 before Processing the Personal Data transferred;
- 5.4. that the Data Importer will promptly notify the Data Exporter about:
- 5.5. any legally binding request for disclosure of the Personal Data by a law enforcement authority unless otherwise prohibited, such as a prohibition under criminal law to preserve the confidentiality of a law enforcement investigation;
  - 5.5.1. any accidental or unauthorised access; and
  - 5.5.2. any request received directly from the Data Subjects without responding to that request, unless it has been otherwise authorised to do so;
- 5.6. to deal promptly and properly with all inquiries from the Data Exporter relating to its Processing of the Personal Data subject to the transfer and to abide by the advice of the Supervisory Authority with regard to the Processing of the data transferred;
- 5.7. at the request of the Data Exporter to submit its data-processing facilities for audit of the Processing activities covered by this DP Agreement which shall be carried out by the Data Exporter or an inspection body composed of independent members and in possession of the required professional qualifications bound by a duty of confidentiality, selected by the Data Exporter, where applicable, in agreement with the Supervisory Authority;
- 5.8. to make available to the Data Subject upon request a copy of this DP Agreement, or any existing contract for sub-processing, unless this DP Agreement or contract contain commercial information, in which case it may remove such commercial information, with the exception of Appendix 2 which shall be replaced by a summary description of the Technical and Organisational Security Measures in those cases where the Data Subject is unable to obtain a copy from the Data Exporter;

- 5.9. that, in the event of sub-processing, it has previously informed the Data Exporter and obtained its prior written consent;
- 5.10. that the Processing services by the Sub-processor will be carried out in accordance with Section 11;
- 5.11. to send promptly a copy of any Sub-processor agreement it concludes under this DP Agreement to the Data Exporter.

## **6. Liability.**

- 6.1. [\*\*\*]

## **7. Mediation and Jurisdiction.**

- 7.1. The Data Importer agrees that if the Data Subject invokes against it third-party beneficiary rights and/or claims compensation for damages under this DP Agreement, the Data Importer will accept the decision of the Data Subject:
  - 7.1.1. to refer the dispute to mediation, by an independent person or, where applicable, by the Supervisory Authority; or
  - 7.1.2. to refer the dispute to the courts in the Member State in which the data exporter is established.
- 7.2. The parties agree that the choice made by the Data Subject will not prejudice his substantive or procedural rights to seek remedies in accordance with other provisions of national or international law.

## **8. Cooperation with Supervisory Authorities.**

- 8.1. The Data Exporter agrees to deposit a copy of this contract with the Supervisory Authority if it so requests or if such deposit is required under the Applicable Data Protection Law.
- 8.2. The parties agree that the Supervisory Authority has the right to conduct an audit of the Data Importer, and of any Sub-processor, which has the same scope and is subject to the same conditions as would apply to an audit of the Data Exporter under the Applicable Data Protection Law.
- 8.3. The Data Importer shall promptly inform the Data Exporter about the existence of legislation applicable to it or any Sub-processor preventing the conduct of an audit of the Data Importer, or any Sub-processor, pursuant to Section 8.2. In such a case the Data Exporter shall be entitled to take the measures foreseen in Section 5.2.

## **9. Governing Law.**

This DP Agreement shall be governed by the law of the country in which the Data Exporter is established.

## **10. Variation of the Contract.**

The parties undertake not to vary or modify this DP Agreement. This does not preclude the parties from adding clauses on business related issues where required as long as they do not contradict any Clause or Section.

## **11. Sub-processing.**

- 11.1. The Data Importer shall not subcontract any of its Processing operations performed on behalf of the Data Exporter under this DP Agreement without the prior written consent of the Data Exporter or unless conducted by the Data Exporter. Where the Data Importer subcontracts its obligations under this DP Agreement, with the consent of the Data Exporter, it shall do so only by way of a written agreement with the Sub-processor which imposes the same obligations on the Sub-processor as are imposed on the Data Importer under this DP Agreement. Where the Sub-processor fails to fulfill its data protection obligations under such written agreement the Data Importer shall remain fully liable to the Data Exporter for the performance of the Sub-processor's obligations under such agreement.
- 11.2. The prior written contract between the Data Importer and the Sub-processor shall also provide for a third-party beneficiary clause as laid down in Section 3 for cases where the Data Subject is not able to

bring the claim for compensation referred to in Section 6.1 against the Data Exporter or the Data Importer because they have factually disappeared or have ceased to exist in law or have become insolvent and no successor entity has assumed the entire legal obligations of the Data Exporter or Data Importer by contract or by operation of law. Such third-party liability of the Sub-processor shall be limited to its own Processing operations under this DP Agreement and any associated contract for the sub-processing.

- 11.3. The provisions relating to data protection aspects for sub-processing of the contract referred to in Section 11.1 shall be governed by the law of the country in which the Data Exporter is established.
- 11.4. The Data Exporter shall keep a list of sub-processing agreements concluded under this DP Agreement and notified by the Data Importer pursuant to Section 5.10, which shall be updated at least once a year. The list shall be available to the Data Exporter's data protection Supervisory Authority.

**12. Obligation after the Termination of Personal Data-processing Services.**

- 12.1. The parties agree that on the termination of the provision of data-processing services, the Data Importer and the Sub-processor shall, at the choice of the Data Exporter, return all the Personal Data transferred and the copies thereof to the Data Exporter or shall destroy all the Personal Data and certify to the Data Exporter that it has done so, unless legislation imposed upon the Data Importer prevents it from returning or destroying all or part of the Personal Data transferred. In that case, the Data Importer warrants that it will guarantee the confidentiality of the Personal Data transferred and will not actively Process the Personal Data transferred anymore.
- 12.2. The Data Importer and the Sub-processor warrant that upon request of the Data Exporter and/or of the Supervisory Authority, it will submit its data-processing facilities for an audit of the measures referred to in Section 12.1.

Dated: June 14, 2021

*For the Data Importer*

*For the Data Exporter*

/s/ Karen Barker June 15, 2021  
Karen Barker

Senior VP, Europe  
Premier Research Group Ltd.  
250 South Oak Way  
Green Park, Reading  
Berkshire, RG2 6UG  
United Kingdom

/s/ Remi Barbier  
Name

\_Remi Barber - President & CEO\_\_\_\_\_  
Position

Cassava Sciences, Inc.  
7801 N. Capital of Texas Hwy, Suite 260, Austin,  
TX 78731

/s/ Sean Russell June 14, 2021

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Sean Russell

Chief Commercial Officer  
Premier Research International LLC  
3800 Paramount Parkway  
Suite 400  
Morrisville, NC 27560-6949

**APPENDIX 1**  
**To the Standard Contractual Clauses (This DP Agreement)**

This Appendix forms part of the Clauses and must be completed and signed by the parties.  
The Member States may complete or specify, according to their national procedures, any additional necessary information to be contained in this Appendix

**Data exporter**

The data exporter is an organization that has executed the Standard Contractual Clauses as a data exporter who is the data controller for data processed by the data importer.

**Data importer**

The data importer is an organization that has executed the Standard Contractual Clauses as a data importer providing clinical research services to the data exporter.

**Data subjects**

The personal data transferred concern the following categories of data subjects:

The data exporter may submit personal data to the data importer or cause personal data to be processed by the data importer on behalf of the data exporter, which may include, but is not limited to personal data relating to the following categories of data subjects:

- employees and contractors of data exporter
- employees and contractors of data exporter's clients and business associates
- trial subjects participating in clinical trials run by data exporter
- trial participants conducting the clinical trials run by data exporter
- other individuals involved in the data exporters' business activities

**Categories of data**

The personal data transferred concern the following categories of data (please specify):

Data exporter may submit personal data to the data importer or cause personal data to be processed by the data importer on behalf of the data exporter, which may include, but is not limited to personal data relating to the following categories of data:

- name, professional contact information (email, phone number, etc).
- home address and personal contact information
- government-issued identification and tax numbers
- previous work and educational history and qualifications
- other categories of data as required by business requirements and at the discretion of the data exporter

**Special categories of data (if appropriate)**

The personal data transferred concern the following special categories of data (please specify):

- pseudonymised demographic information such as race and gender
- pseudonymised information about trial subjects' quality of life and personal life
- pseudonymised health related information
- pseudonymised biometric and genetic data
- other categories of data as required by the clinical trial protocol and at the discretion of the data exporter

**DESCRIPTION OF PROCESSING ACTIVITIES**

Data is processed under the Agreement dated June 11, 2021 to provide the services which include provision of clinical research services.

Dated: June 15, 2021

*For the Data Importer*

*For the Data Exporter*

/s/ Karen Barker

Karen Barker

Senior VP, Europe

Premier Research Group Ltd  
250 South Oak Way  
Green Park, Reading  
Berkshire, RG2 6UG  
United Kingdom

For the Data Importer

/s/ Remi Barbier

Name

Remi Barber - President & CEO  
Position

Cassava Sciences, Inc.  
7801 N. Capital of Texas Hwy, Suite 260, Austin,  
TX 78731

/s/ Sean Russell June 14, 2021  
Sean Russell

Chief Commercial Officer  
Premier Research International LLC  
3800 Paramount Parkway  
Suite 400  
Morrisville, NC 27560-6949

**APPENDIX 2**  
**To the Standard Contractual Clauses (This DP Agreement)**  
**Technical and Organisational Security Measures**

**Description of the Technical and Organisational Security Measures implemented by the Data Importer**

**Premier Research Group**  
**Global Regulatory Security Compliance – Framework**

To ensure global compliance Premier Research operates under a standard set of policies, operating procedures, and working guideline documents that provide a framework for the information security environment. Security practices are implemented as a basis for the information security program and a defense-in-depth strategy is employed to assure the confidentiality, integrity, and availability of Personal Data.

Premier Research’s global privacy and data protection practices encompasses guidance for all data and sensitive information that are directly or indirectly captured, stored, processed and archived by Premier Research.

Premier Research conducts its business in compliance with the respective national and international data protection and confidentiality regulations and laws governing the performance of clinical research and processing of personal data, including but not limited to.

- United States Food and Drug Administration 21 CFR Part 11
- Health Insurance Portability and Accountability Act of 1996 (HIPAA)
- European Union (EU) 2016/679 (General Data Protection Regulation or GDPR).

**Global Regulatory Security Compliance – Policies and Procedures**

To ensure information security, Premier Research has various policies, standard operating procedures that contribute to our privacy and security posture.

Policies and standard operating procedures include subject areas such as Data Protection, Trial Subject Confidentiality, Compliance of IT Systems, Incident Response and Disaster Recovery. Staff are required to train on these policies and standard operating procedures as appropriate for their job role. All staff are required to undertake Data Protection Awareness Training.

**Global Regulatory Security Compliance – Controls**

*Third Party Vendors*

Premier Research evaluates the security practices of third-party vendors with which it does business to ensure its security goals and compliance are maintained.

Premier Research uses reputable third party vendor-provided Software as a Service (SaaS) or Platform as a Service (PaaS) that is built on tried and tested hosting platforms such as Microsoft Azure that conform to the highest industry standard security protocols. Details of specific vendors working to provide services to you are available upon request.

*Location of Processing*

Premier Research utilizes assets that are located in data centers based in the United States. These assets are accessed by Premier Research office and home-based staff around the world, wherever we have a presence. A full list of Premier Research group companies is attached in Appendix 3, and is supplemented from time to time by notice to our clients.



Premier Research also has carefully selected alliance partners and sub-CROs around the world who assist us with delivering our global services. Details of specific affiliates and Sub-CROs working to provide services to you are available upon request.

Where personal data is being processed outside of the European Economic Area, Premier Research implements appropriate and legal transfer mechanisms such as these clauses or adherence to an approved Code of Conduct.

*Security Controls*

Premier Research utilizes numerous security systems ranging from end-user, network based and server/ data.

The network edge is protected using a layered security approach which includes Firewalls, Application Firewalls, Antivirus/Malware scanning, Vulnerability scanning and various monitoring solutions.

A layered security approach is employed which protects the public facing resources (WWW, DNS, SFTP) to minimize exposure, risk and vulnerabilities.

All connections with Clients and affiliates are encrypted via VPN or TLS based on needs utilizing industry standard security ciphers for the highest level of encryption.

Vulnerability assessments are performed and remediated prior to services entering production and done on a periodic basis afterwards.

Remote access to the corporate network utilizes industry recognized security protocols including IPSEC and SSLVPN.

All security monitoring and incident management occurs via a central anti-malware, firewall, application firewall, and vulnerability consoles.

Database Monitoring & Auditing services deliver automated and scalable database solutions that monitor and audit all access to Personal Data across the diverse platforms.

Security Access controls are used to limit and control access to physical locations, systems and files.

Dated: \_\_\_June 15, 2021\_\_\_\_\_

*For the Data Importer*

*For the Data Exporter*

/s/ Karen Barker

Karen Barker

Senior VP, Europe

Premier Research Group Ltd

/s/ Remi Barbier

Name

\_ Remi Barber - President & CEO\_\_\_\_\_

Position

Cassava Sciences, Inc.

250 South Oak Way  
Green Park, Reading  
Berkshire, RG2 6UG  
United Kingdom

7801 N. Capital of Texas Hwy, Suite 260, Austin,  
TX 78731

*For the Data Importer*

/s/ Sean Russell June 14, 2021

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Sean Russell

Chief Commercial Officer  
Premier Research International LLC  
3800 Paramount Parkway  
Suite 400  
Morrisville, NC 27560-6949

**APPENDIX 3**  
**To the Standard Contractual Clauses (This DP Agreement)**  
**List of Data Importers**

| <b>Country</b>      | <b>Company</b>   |
|---------------------|--|
| Australia<br>(AU)   | Premier Research Australia PTY Limited                             |
| Canada<br>(CN)      | Premier Research Group Canada Limited                              |
| China<br>(CN)       | <b>Branch of Singapore</b><br>Premier Research (Shanghai) Co., Ltd |
| Israel<br>(IL)      | Premier Research Israel Ltd.                                       |
| Russia<br>(RU)      | Premier Research LLC   |
| Serbia<br>(RS)      | Premier Research S doo   |
| Singapore<br>(SG)   | Premier Research Singapore Pte. Ltd.                               |
| South Korea<br>(KR) | Premier Research Group Ltd South Korea <u>Branch</u>               |
| Taiwan<br>(TW)      | Premier Research Group Limited Taiwan <u>Branch</u>                |
| Ukraine<br>(UA)     | Premier Research Ukraine Ltd.                                      |
| India<br>(IN)       | Premier Research (India) Private Limited                           |

**Exhibit D**

**Volume Rebate and Non-Competitive Award Discounts**

[\*\*\*]

**EXHIBIT E:  
Client Signatory Authorization**

For the purposes of Section 2.1 [“Work Orders”] and Section 2.2 [“Amendments”], Premier shall at all times require prior signatory authorization from Client.

Full-time employees of Cassava Sciences who hold the following titles are authorized and duly empowered to bind the Client for Work Orders, Amendments and other such work matters under this Master Services Agreement up to the following dollar limits:

|     |     |
|-----|-----|
| *** | *** |
| *** | *** |
| *** | *** |
| *** | *** |

No other persons, advisor or consultant has authority to sign any document that creates a binding obligation between the Client and Premier.

Client reserves the right to modify Exhibit E from time-to-time upon written notice to Premier signed by Client’s Chief Executive Officer.

\* \*\*\*

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Remi Barbier, certify that:

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

/s/ REMI BARBIER

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Remi Barbier,  
Chairman of the Board of Directors,  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: August 4, 2021

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CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Eric J. Schoen, certify that:

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

/s/ ERIC J. SCHOEN

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Eric J. Schoen,  
Chief Financial Officer  
(Principal Financial Officer)

Date: August 4, 2021

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CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL  
OFFICER PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002  
(18 U.S.C. Section 1350)

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Cassava Sciences, Inc. (the "Company"), hereby certifies that to the best of such officer's knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2021, and to which this certification is attached as Exhibit 32.1 (the "Periodic 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 Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 4, 2021

/s/ REMI BARBIER

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Remi Barbier,  
Chairman of the Board of Directors,  
President and Chief Executive Officer

/s/ ERIC J. SCHOEN

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Eric J. Schoen,  
Chief Financial Officer

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