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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, 2024
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period from _____ to _____

Commission File Number: 001-41905

Cassava Sciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**91-1911336**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*

6801 N. Capital of Texas Highway, Building 1; Suite 300, 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 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 ☑	Accelerated Filer ☐
Non-accelerated Filer ☐	Smaller Reporting Company ☐
	Emerging Growth Company ☐

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

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

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	47,976,166 Shares Outstanding as of August 5, 2024

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PART I. FINANCIAL INFORMATION

Item 1. ***Financial Statements***

CASSAVA SCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, In thousands, except share and par value data)

	June 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 207,291	$ 121,136
Prepaid expenses and other current assets	14,831	8,497
Total current assets	222,122	129,633
Property and equipment, net	21,364	21,854
Intangible assets, net	82	176
Total assets	$ 243,568	$ 151,663
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 52,552	$ 10,573
Accrued development expense	1,596	3,037
Accrued compensation and benefits	218	200
Other current liabilities	228	385
Total current liabilities	54,594	14,195
Commitments and contingencies (Notes 9, 10 and 11)		
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; 47,976,166 and 42,236,919 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	48	42
Additional paid-in capital	538,497	518,195
Accumulated deficit	(349,571)	(380,769)
Total stockholders' equity	188,974	137,468
Total liabilities and stockholders' equity	$ 243,568	$ 151,663

See accompanying notes to condensed consolidated financial statements.

CASSAVA SCIENCES, INC.

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

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 15,198	$ 24,969	$ 31,431	$ 47,089
General and administrative	46,204	3,808	49,905	8,200
Total operating expenses	61,402	28,777	81,336	55,289
Operating loss	(61,402)	(28,777)	(81,336)	(55,289)
Interest income	2,316	2,198	4,092	4,249
Other income, net	99	203	259	393
Gain from change in fair value of warrant liabilities	65,142	—	108,183	—
Net income (loss)	$ 6,155	$ (26,376)	$ 31,198	$ (50,647)
Shares used in computing net income (loss) per share, basic	46,202	41,793	44,601	41,766
Net income (loss) per share, basic	$ 0.13	$ (0.63)	$ 0.70	$ (1.21)
Numerator, diluted:				
Net income (loss)	$ 6,155	$ (26,376)	$ 31,198	$ (50,647)
Adjustment for change in fair value of warrant liabilities	—	—	(43,793)	—
Adjusted numerator, diluted	$ 6,155	$ (26,376)	$ (12,595)	$ (50,647)
Shares used in computing net income (loss) per share, diluted	46,202	41,793	45,152	41,766
Net income (loss) per share, diluted	$ 0.13	$ (0.63)	$ (0.28)	$ (1.21)

See accompanying notes to condensed consolidated financial statements.

CASSAVA SCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited, in thousands, except share data)

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Par value			
Balance at December 31, 2022	41,735,557	$ 42	$ 511,049	$ (283,552)	$ 227,539
Stock-based compensation for:					
Stock options for employees	—	—	650	—	650
Stock options for non-employees	—	—	23	—	23
Issuance of common stock pursuant to exercise of stock options	13,878	—	64	—	64
Net loss	—	—	—	(24,271)	(24,271)
Balance at March 31, 2023	41,749,435	$ 42	$ 511,786	$ (307,823)	$ 204,005
Stock-based compensation for:					
Stock options for employees	—	—	812	—	812
Stock options for non-employees	—	—	23	—	23
Issuance of common stock pursuant to exercise of stock options	170,092	—	889	—	889
Net loss	—	—	—	(26,376)	(26,376)
Balance at June 30, 2023	41,919,527	$ 42	$ 513,510	$ (334,199)	$ 179,353
Balance at December 31, 2023	42,236,919	$ 42	$ 518,195	$ (380,769)	$ 137,468
Stock-based compensation for:					
Stock options for employees	—	—	2,312	—	2,312
Stock options for non-employees	—	—	23	—	23
Issuance of warrants	—	—	(113,363)	—	(113,363)
Issuance of common stock pursuant to exercise of warrants	1,011,497	1	22,159	—	22,160
Derecognition of warrant liabilities upon exercise of warrants	—	—	4,954	—	4,954
Net income	—	—	—	25,043	25,043
Balance at March 31, 2024	43,248,416	$ 43	$ 434,280	$ (355,726)	$ 78,597
Stock-based compensation for:					
Stock options for employees	—	—	2,581	—	2,581
Stock options for non-employees	—	—	23	—	23
Issuance of common stock pursuant to exercise of warrants	4,727,750	5	101,387	—	101,392
Derecognition of warrant liabilities upon exercise of warrants	—	—	226	—	226
Net income	—	—	—	6,155	6,155
Balance at June 30, 2024	47,976,166	$ 48	$ 538,497	$ (349,571)	$ 188,974

See accompanying notes to condensed consolidated financial statements.

CASSAVA SCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	Six months ended June 30, 2024	2023
Cash flows from operating activities:		
Net income (loss)	$ 31,198	$ (50,647)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,939	1,508
Gain from change in fair value of warrant liabilities	(108,183)	—
Depreciation	496	544
Amortization of intangible assets	117	238
Changes in operating assets and liabilities:		
Prepaid and other current assets	(6,334)	4,116
Operating lease right-of-use assets and liabilities	—	(17)
Accounts payable and accrued expenses	41,979	6,661
Accrued development expense	(1,441)	4,764
Accrued compensation and benefits	18	50
Other liabilities	(157)	(396)
Net cash used in operating activities	(37,368)	(33,179)
Cash flows from investing activities:		
Purchases of property and equipment	(29)	(351)
Net cash used in investing activities	(29)	(351)
Cash flows from financing activities:		
Proceeds from exercise of common stock warrants, net of exercise costs	123,552	—
Proceeds from issuance of common stock upon exercise of stock options	—	953
Net cash provided by financing activities	123,552	953
Net increase (decrease) in cash and cash equivalents	86,155	(32,577)
Cash and cash equivalents at beginning of period	121,136	201,015
Cash and cash equivalents at end of period	$ 207,291	$ 168,438
Supplemental cash flow information:		
Non-cash financing activities		
Issuance of warrants resulting in recognition of warrant liabilities	113,363	—
Derecognition of warrant liabilities upon exercise of warrants	(5,180)	—

See accompanying notes to condensed consolidated financial statements.

Cassava Sciences, Inc.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

Note 1. General and Liquidity

Cassava Sciences, Inc. and its wholly-owned subsidiary (collectively referred to as 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 consolidated 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. All intercompany transactions and balances have been eliminated in consolidation. Accordingly, the condensed consolidated financial statements do not include all of the information and footnotes required by GAAP for complete consolidated 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, 2024 are not necessarily indicative of the results that may be expected for any other interim period or for the year 2024. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

Liquidity

The Company has incurred significant net losses and negative cash flows since inception, and as a result has an accumulated deficit of $349.6 million at June 30, 2024. 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 consolidated 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 consolidated 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 common stock warrant liabilities, clinical trials and manufacturing agreements. 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 deposit, 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, 2024 and December 31, 2023.

The fair value of common stock warrants of $6.71 per warrant was determined at distribution on January 3, 2024 using a Monte Carlo valuation model since the warrants were not traded on the open market on January 3, 2024. Warrant trading on Nasdaq began on January 4, 2024. Quantitative information regarding Level 3 fair value measurements for common stock warrants are as follows:

Exercise price per warrant	$	33.00
Conversion rate - common shares per warrant		1.50
Closing price of common stock	$	23.72
Volatility		75%
Risk-free interest rate		5.40%
Expected life of option (in years)		0.3
Dividend yield		zero

The common stock warrants stopped trading on Nasdaq after May 2, 2024 and subsequently had little or no market activity. As of May 7, 2024, the warrants were presumed to have no value since they were redeemed for a nominal payment of $0.001 per warrant.

Business Segments

The Company reports segment information based on how it internally evaluates the operating performance of its business units, or segments. The Company’s operations are confined to one business segment: the development of novel drugs and diagnostics.

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 to calculate the fair value of stock options, using the single-option award approach and straight-line attribution method. This model requires the input of subjective assumptions including expected stock price volatility, expected life and estimated forfeitures of each award. These assumptions consist of estimates of future market conditions, which are inherently uncertain, and therefore, are subject to management's judgment. 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 Income (Loss) per Share

Basic net income (loss) per common share is computed by dividing the net income (loss) available to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net income (loss) per common share is computed by dividing the net income (loss) available to common stockholders by the weighted-average number of common shares outstanding and potentially dilutive securities outstanding during the period using the treasury stock method. Potentially dilutive securities are excluded from the computations of diluted earnings per share if their effect would be antidilutive. A net loss causes all potentially dilutive securities to be antidilutive. Potentially dilutive securities consist of outstanding common stock options, warrants and Performance Awards. There is no difference between the Company's net income (loss) and comprehensive net income (loss). The numerators and denominators in the calculation of basic and diluted net loss per share were as follows (in thousands, except net loss per share data):

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Numerator, basic:				
Net income (loss)	$ 6,155	$ (26,376)	$ 31,198	$ (50,647)
Denominator, basic:				
Weighted average common shares outstanding	46,202	41,793	44,601	41,766
Net income (loss) per share, basic	$ 0.13	$ (0.63)	$ 0.70	$ (1.21)
Numerator, diluted:				
Net income (loss)	$ 6,155	$ (26,376)	$ 31,198	$ (50,647)
Adjustment for change in fair value of warrant liabilities	—	—	(43,793)	—
Adjusted numerator, diluted	$ 6,155	$ (26,376)	$ (12,595)	$ (50,647)
Denominator, diluted:				
Weighted average common shares outstanding	46,202	41,793	44,601	41,766
Dilutive effect of common stock warrants	—	—	551	—
Weighted average dilutive common shares	46,202	41,793	45,152	41,766
Net income (loss) per share, diluted	$ 0.13	$ (0.63)	$ (0.28)	$ (1.21)
Dilutive common stock options excluded from net income (loss) per share, diluted	2,703	2,001	2,674	2,018
Dilutive Performance Awards excluded from net income (loss) per share, diluted	7	7	7	7

The Company excluded common stock options and Performance Awards outstanding for the three months ended June 30, 2024 and 2023 from the calculation of net loss per share, diluted, because the effect of including outstanding options and Performance Awards would have been anti-dilutive. The Company excluded common stock options and Performance Awards outstanding for the six months ended June 30, 2024 and 2023 from the calculation of net loss per share, diluted, because the effect of including outstanding options and Performance Awards would have been anti-dilutive. Warrants were included for the calculation of net loss per share, diluted, for the six months ended June 30, 2024 assuming each warrant was exercisable for one and one-half shares of common stock.

Warrant Liabilities

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, "Distinguishing Liabilities from Equity" ("ASC 480"), and ASC 815, "Derivatives and Hedging" ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own shares, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value of the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of liability classified warrants are recognized as a non-cash gain or loss on the statements of operations. Costs associated with issuing the warrants classified as derivative liabilities are charged to operations when the warrants are issued.

Fair Value of Financial Instruments

Financial instruments include accounts payable, accrued expenses, accrued development expense and other 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, accrued expenses, accrued development expense and other liabilities are at cost, which approximates fair value due to the short maturity of those instruments.

Research Contracts, Prepaids 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. Related payments are recorded as research and development expenses as incurred. The Company records prepaids and accruals for estimated ongoing research costs. When evaluating the adequacy of prepaid expenses and 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 prepaid and accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical prepaid and 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 "CIB Plan") to incentivize Plan participants. Awards under the CIB Plan are accounted for as liability awards under ASC 718 "*Stock-based Compensation*". The fair value of each potential CIB Plan award will be determined once a grant date occurs and will be remeasured each reporting period. Compensation expense associated with the CIB Plan will be recognized over the expected achievement period for each CIB Plan award, when a Performance Condition (as defined below) is considered probable of being met. See Note 10 for further discussion of the CIB 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 consolidated 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.

Property and Equipment

Property and equipment are recorded at cost, net of accumulated depreciation. Depreciation is recorded using the straight-line method over the estimated useful lives of the assets. Owned buildings and related improvements have estimated useful lives of 39 years and approximately 10 years, respectively. Tenant improvements are amortized using the straight-line method over the useful lives of the improvements or the remaining term of the corresponding leases, whichever is shorter.

Property and equipment are reviewed for impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. If property and equipment are considered to be impaired, an impairment loss is recognized.

Intangible Assets

Acquired intangible assets are recorded at fair value at the date of acquisition and primarily consist of lease-in-place agreements and leasing commissions. Intangible assets are amortized over the estimated life of the lease-in-place agreements. Intangible assets also include leasing commissions which are amortized over the life of the lease agreement.

Intangible assets are reviewed for impairment on an annual basis, and when there is reason to believe that their values have been diminished or impaired. If intangible assets are considered to be impaired, an impairment loss is recognized.

Insurance Recoveries

We record proceeds from our insurance policies when the loss event has occurred, and proceeds are estimable and probable of being recovered. Insurance recoveries and proceeds received are recorded as a reduction to general and administrative expense. There was approximately $5.8 million of insurance recoveries recorded during the three months ended June 30, 2024. There were no insurance recoveries recorded during the three months ended June 30, 2023. There was approximately $8.8 million and $0.1 million of insurance recoveries recorded during the six months ended June 30, 2024 and 2023, respectively. The applicable policy has a $10.0 million recovery limit.

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 consolidated 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.

Recently Issued Accounting Pronouncements

In November 2023, the FASB issued Accounting Standards Update, or ASU, No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. This standard requires disclosure of significant segment expenses and other segment items by reportable segment. The ASU becomes effective for annual periods beginning in 2024 and interim periods in 2025. The Company is evaluating the impact of adopting this standard on its consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This standard enhances disclosures related to income taxes, including the rate reconciliation and information on income taxes paid. The ASU becomes effective January 1, 2025. The Company is evaluating the impact of adopting this standard on its consolidated financial statements and disclosures.

Note 3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets at June 30, 2024 and December 31, 2023 consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Prepaid insurance	$ 5	$ 759
Contract research organization and other deposits	7,432	6,489
Interest receivable	1,433	962
Insurance recoveries	5,800	—
Other	161	287
Total prepaid expenses and other current assets	$ 14,831	$ 8,497

Contract research organization and other deposits represent cash payments made to vendors in excess of expenses incurred.

Note 4. Real Property and Other Income, Expense

The Company owns a two-building office complex in Austin, Texas, a portion of which serves as its corporate headquarters. This property is intended to accommodate the Company's potential growth and expansion of its operations in the coming years. Maintenance, physical facilities, leasing, property management and other key responsibilities related to property ownership are outsourced to professional real-estate managers. The office complex has approximately 90,000 square feet of rentable space. At June 30, 2024, the Company occupied approximately 25% of the property with the remainder either leased or available for lease to third parties.

The Company records the net income from building operations and leases as other income, net, as leasing is not core to the Company's operations. Building depreciation and amortization for space not occupied by the Company is included in general and administrative expense. Building depreciation and amortization for space occupied by the Company is allocated between general and administrative expense and research and development expense. Components of other income, net, for the periods presented were as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Lease revenue	$ 314	$ 559	$ 717	$ 1,116
Property operating expenses	(215)	(356)	(458)	(723)
Other income, net	$ 99	$ 203	$ 259	$ 393

Note 5. Property and equipment

The components of property and equipment, net, as of June 30, 2024 and December 31, 2023 were as follows (in thousands):

	June 30, 2024	December 31, 2023
Land	$ 3,734	$ 3,734
Buildings	15,980	15,980
Site improvements	494	494
Tenant improvements	3,062	3,062
Furniture and equipment	873	868
Gross property and equipment	$ 24,143	$ 24,138
Accumulated depreciation	(2,779)	(2,284)
Property and equipment, net	$ 21,364	$ 21,854

Depreciation expense for property and equipment was $244,000 and $272,000 for the three months ended June 30, 2024 and 2023, respectively. Depreciation expense for property and equipment was $496,000 and $544,000 for the six months ended June 30, 2024 and 2023, respectively.

Note 6. Intangible assets

The components of intangible assets, net, as of June 30, 2024 and December 31, 2023 were as follows (in thousands):

	June 30, 2024	December 31, 2023
Lease-in-place agreements	$ 1,053	$ 1,053
Leasing commissions and other	317	293
Gross intangible assets	$ 1,370	$ 1,346
Accumulated amortization	(1,288)	(1,170)
Intangible assets, net	$ 82	$ 176

Amortization expense for intangible assets was $56,000 and $119,000 for the three months ended June 30, 2024 and 2023, respectively. Amortization expense for intangible assets was $117,000 and $238,000 for the six months ended June 30, 2024 and 2023, respectively.

Amortization expense for finite-lived intangible assets as of June 30, 2024 is expected to be as follows (in thousands):

For the year ending December 31,	
2024	$ 60
2025	$ 11
2026	$ 8
2027	3
Total amortization	$ 82

Note 7. Stockholders' Equity and Stock-Based Compensation Expense

Common Stock Warrant Distribution

See Notes 2 and 12 regarding the distribution of common stock warrants on January 3, 2024.

At-the-Market Common Stock Offering

On May 1, 2023, the Company entered into 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 $200 million in common stock pursuant to a shelf registration statement that was filed with the U.S. Securities and Exchange Commission (the "SEC") on May 1, 2023 and became effective immediately upon filing. The Company is obligated to pay a commission of up to 3% 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, 2024.

In March 2020, the Company entered into an at-the-market offering program ("2020 Program") 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 SEC on May 5, 2020. The Company gave notice of termination for the 2020 Program on April 26, 2023, which was effective May 1, 2023. There were no common stock sales under the 2020 Program through its termination.

Stock Option and Performance Award Activity in 2024

During the six months ended June 30, 2024, stock options and unvested Performance Awards outstanding under the Company's stock option plans changed as follows:

	Stock Options	Performance Awards
Outstanding as of December 31, 2023	3,039,029	7,142
Options granted	193,000	—
Options exercised	—	—
Options forfeited/canceled	(154,700)	—
Outstanding as of June 30, 2024	3,077,329	7,142

The weighted average exercise price per share of options outstanding at June 30, 2024 was $14.57. As outstanding options vest over the current remaining vesting period of 2.4 years, the Company expects to recognize stock-based compensation expense of $22.6 million. If and when outstanding Performance Awards vest, the Company will recognize stock-based compensation expense of $0.1 million over the implicit service period.

During the three and six months ended June 30, 2024, there were no stock options exercised.

During the three months ended June 30, 2023, there were 262,158 stock options exercised. Of the stock options exercised, 92,066 stock options were net settled in satisfaction of the exercise price, with no cash proceeds received. Cash proceeds to the Company for options not net settled totaled $889,000 during the three months ended June 30, 2023.

During the six months ended June 30, 2023, there were 281,175 stock options exercised. Of the stock options exercised, 97,205 stock options were net settled in satisfaction of the exercise price, with no cash proceeds received. Cash proceeds to the Company for options not net settled totaled $953,000 during the six months ended June 30, 2023.

Stock-based Compensation Expense in 2024

During the three and six months ended June 30, 2024 and 2023, the Company's stock-based compensation expense was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Research and development	$ 972	$ 392	$ 1,945	$ 781
General and administrative	1,632	443	2,994	727
Total stock-based compensation expense	$ 2,604	$ 835	$ 4,939	$ 1,508

2018 Equity Incentive Plan

The Company's Board of Directors (the "Board") or a designated committee of the Board is responsible for administration of the Company's 2018 Omnibus Incentive Plan, as amended (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, as amended in May 2022, provides for issuance of up to 5,000,000 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 8. Income Taxes

The Company did not provide for income taxes during the three and six months ended June 30, 2024, because it has projected a taxable net loss for the full year 2024 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, 2023.

Note 9. 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.

Note 10. 2020 Cash Incentive Bonus Plan

In August 2020, the Board approved the CIB Plan. The CIB Plan was established to promote the long-term success of the Company by creating an "at-risk" cash bonus program that rewards CIB Plan participants with additional cash compensation in lockstep with significant increases in the Company's market capitalization. The CIB Plan is considered "at-risk" because CIB Plan participants will not receive a cash bonus unless the Company's market capitalization increases significantly and certain other conditions specified in the CIB Plan are met. Specifically, CIB 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 CIB Plan. Because of the inherent discretion and uncertainty regarding these requirements, the Company has concluded that a CIB Plan grant date has not occurred as of June 30, 2024.

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

As of December 31, 2022, the Company's independent directors were participants in the CIB Plan. However, effective March 16, 2023, the Board amended the CIB Plan to remove all independent directors as participants in the CIB Plan and the independent directors consented to such removal. The independent directors' share of potential benefits under the CIB Plan were completely forfeited to the Company and will not be allocated to any other participant under the CIB Plan. The Company's independent directors have not received, and as a result of such amendment will never receive, any payments under the CIB Plan.

The Company's market capitalization for purposes of the CIB Plan is determined based on either (1) the closing price of one share of the Company's common stock 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. Any warrants outstanding are excluded from the determination of market capitalization. This constitutes a market condition under applicable accounting guidance.

The CIB 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 CIB 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 CIB Plan. Each Valuation Milestone must be achieved and maintained for no less than 20 consecutive trading days for CIB Plan participants to be eligible for a potential cash bonus award. Approximately 67% 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 $111.4 million up to a hypothetical maximum of $289.7 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 CIB Plan participants will ever be paid a cash bonus that is awarded under the CIB Plan, even if the Company's market capitalization increases significantly.

The CIB 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 CIB 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.

In October 2020, the Company achieved the first Valuation Milestone. Subsequently in 2020, the Compensation Committee approved a potential cash bonus award of $6.5 million in total for all CIB Plan participants (after taking into account the March 2023 CIB Plan amendment), subject to future satisfaction of a Performance Condition.

During the year ended December 31, 2021, the Company achieved 11 additional Valuation Milestones triggering potential Company obligations to all CIB Plan participants from a minimum of $74.9 million up to a hypothetical maximum of $202.3 million (after taking into account the March 2023 CIB Plan amendment), to be determined, approved and allocated by the Compensation Committee and contingent upon future satisfaction of a Performance Condition. However, no compensation expense was recorded since no grant date has occurred and no Performance Conditions are considered probable of being met. There is no continuing service requirement for CIB Plan participants once the Compensation Committee approves a cash bonus award.

No Valuation Milestones were achieved during the years ended December 31, 2023 and 2022 or the six months ended June 30, 2024.

No actual cash payments were authorized or made to participants under the CIB Plan through the date of filing of this Form 10-Q.

Note 11. Contingencies

The Company is, and from time to time, the Company may become, involved in litigation or other legal proceedings and claims, including U.S. government inquiries, investigations and Citizen Petitions submitted to FDA. In addition, the Company has received, and from time to time may receive, inquiries from government authorities relating to matters arising from the ordinary course of business. The outcome of these proceedings is inherently uncertain. Regardless of outcome, legal proceedings can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors. At this time, no assessment can be made as to their likely outcome or whether the outcome will be material to the Company other than as disclosed below. The Company believes that its total provisions for legal matters are adequate based upon currently available information.

Update on Government Investigations

Beginning in August 2021, the Company has received subpoenas, a Civil Investigative Demand ("CID") and other requests for documents and information from the Department of Justice and document requests from the Securities and Exchange Commission, each seeking corporate information and documents concerning the research and development of simufilam and/or SavaDx. The Company has been providing documents and information in response to these subpoenas, CID and requests for information and intends to continue to cooperate with these government inquiries. The Company cannot predict the outcome or impact of these ongoing matters, including whether a government authority may pursue an enforcement action against the Company or others.

The Company is in the advanced stages of discussions with the SEC staff to resolve the SEC's nearly three-year investigation of the Company's disclosures regarding its Phase 2b study of simufilam for the treatment of Alzheimer's disease (the "Phase 2b Study"). The Company has reserved a loss contingency of $40 million on its consolidated balance sheet as of June 30, 2024 relating to this potential settlement with the SEC.

The Company continues to cooperate with the DOJ related to conduct alleged in the indictment of Dr. Hoau-Yan Wang announced by the Department of Justice on June 28, 2024.

Securities Class Actions and Shareholder Derivative Actions

Between August 27, 2021 and October 26, 2021, four putative class action lawsuits were filed alleging violations of the federal securities laws by the Company and certain named officers. The complaints rely on allegations contained in Citizen Petitions submitted to FDA and allege that various statements made by the defendants regarding simufilam were rendered materially false and misleading. The Citizen Petitions were all subsequently denied by FDA. These actions were filed in the U.S. District Court for the Western District of Texas. The complaints seek unspecified compensatory damages and other relief on behalf of a purported class of purchasers.

On June 30, 2022, a federal judge consolidated the four class action lawsuits into one case and appointed a lead plaintiff and a lead counsel. Lead plaintiff filed a consolidated amended complaint on August 18, 2022 on behalf of a putative class of purchasers of the Company's securities between September 14, 2020 and July 26, 2022. On May 11, 2023, the court dismissed with prejudice plaintiffs' claims against defendant Nadav Friedmann, PhD, MD, our former Chief Medical Officer and a Company director, who is now deceased, but otherwise denied defendants' motion to dismiss. Defendants filed an answer to the consolidated amended complaint on July 3, 2023. On February 22, 2024, plaintiffs filed a motion to supplement their complaint to extend the putative class period through October 12, 2023. The court granted that Motion on June 12, 2024, and plaintiffs filed a supplemental complaint on June 13, 2023. On March 13, 2024, plaintiffs filed a Motion for Class Certification. The Company has opposed that Motion.

On November 4, 2021, a related shareholder derivative action was filed, purportedly on behalf of the Company, in the U.S. District Court for the Western District of Texas, asserting claims under the U.S. securities laws and state fiduciary duty laws against certain named officers and the members of the Company's Board. This complaint relies on the allegations made in Citizen Petitions that were submitted to (and subsequently denied by) FDA. The complaint alleges, among other things, that the individual defendants exposed the Company to unspecified damages and securities law liability by causing it to make materially false and misleading statements, in violation of the U.S. securities laws and in breach of their fiduciary duties to the Company. The derivative case seeks, among other things, to recover unspecified compensatory damages on behalf of the Company arising out of the individual defendants' alleged wrongful conduct. Although the plaintiff in this derivative case does not seek relief against the Company, the Company has certain indemnification obligations to the individual defendants. Between November 4, 2021 and June 20, 2023, four additional shareholder derivative actions were filed alleging substantially similar claims, two in the U.S. District Court for the Western District of Texas, one in Texas state court (Travis County District Court) and one in the Delaware Court of Chancery. On July 5, 2022, the three actions in the Western District of Texas were consolidated into a single action. All of the foregoing actions are currently stayed pending further developments in the consolidated securities action described above. On November 9, 2023, another shareholder derivative action alleging substantially similar claims was filed in the U.S. District Court for the Western District of Texas. The parties to that case expect that it will be consolidated into the existing consolidated federal court shareholder derivative action.

On February 2, 2024, a putative class action lawsuit was filed, purportedly on behalf of the Company, alleging violations of the federal securities law by the Company and certain named officers. The complaint relies on an October 12, 2023 article that describes a purported leaked report of alleged scientific misconduct by a scientific collaborator of the Company at City University of New York. The complaint alleges that various statements made by the defendants regarding simufilam were rendered materially false and misleading by this article. The action was filed in the U.S. District Court for the Northern District of Illinois. The complaint seeks unspecified compensatory damages and other relief on behalf of a purported class of purchasers of the Company's securities between August 18, 2022 and October 12, 2023. On May 28, 2024, the Northern District of Illinois transferred this action to the Western District of Texas.

Beginning on March 18, 2024, two related shareholder derivative actions were filed, purportedly on behalf of the Company, in the U.S. District Court for the Northern District of Illinois, asserting claims under the U.S. securities laws and state fiduciary duty laws against certain named officers and the members of the Company's Board. The complaints rely on an October 12, 2023 article that describes a purported leaked report of alleged scientific misconduct by a scientific collaborator of the Company at City University of New York. The complaints allege, among other things, that the individual defendants exposed the Company to unspecified damages and securities law liability by causing it to make materially false and misleading statements, in violation of the U.S. securities laws and in breach of their fiduciary duties to the Company. The derivative cases seek, among other things, to recover unspecified compensatory damages on behalf of the Company arising out of the individual defendant's alleged wrongful conduct. Although the plaintiffs in these derivative cases do not seek relief against the Company, the Company has certain indemnification obligations to the individual defendants.

The Company believes the foregoing claims are without merit and intends to defend against these lawsuits vigorously. The Company is unable to estimate the possible loss or range of loss, if any, associated with these lawsuits.

On August 19, 2022, a shareholder derivative action was filed, purportedly on behalf of the Company, in the Delaware Court of Chancery, asserting claims under state fiduciary duty laws against certain named officers and members of the Company's Board. The complaint alleges, among other things, that the individual defendants breached their fiduciary duties by approving the 2020 Cash Incentive Bonus Plan in August 2020. The complaints seek unspecified compensatory damages and other relief. On January 6, 2023, the plaintiffs filed an amended complaint. Defendants filed a partial answer to the amended complaint on March 10, 2023, and moved to partially dismiss the amended complaint on March 14, 2023.

On May 28, 2024, the parties entered into a Stipulation and Agreement of Settlement, Compromise, and Release (the "Stipulation") to resolve the Action. The Stipulation and exhibits thereto, including the proposed Notice of Pendency of Settlement of Class and Derivative Action (the "Notice") and [Proposed] Scheduling Order with Respect to Notice and Settlement Hearing (the "Scheduling Order"), were filed in the Delaware Court of Chancery on May 28, 2024. The Stipulation is subject to final approval by the Delaware Court of Chancery. The Stipulation, if finally approved, will cause the dismissal with prejudice of the Action.

On June 26, 2024, the Delaware Court of Chancery entered the Scheduling Order, which includes approval of the Notice. Resolution of the Action is subject to approval from the Delaware Court of Chancery. The Delaware Court of Chancery set a final settlement hearing for September 9, 2024, at 3:15 p.m. ET in the Delaware Court of Chancery, Leonard L. Williams Justice Center, 500 North King Street, Wilmington, Delaware 19801.

Anti-SLAPP Lawsuit

On August 6, 2024, a lawsuit was filed in the District Court for the Southern District of New York asserting claims under the New York Anti-SLAPP Law. The complaint seeks costs and damages relating to a defamation action filed by the Company against the plaintiffs and subsequently dismissed voluntarily and without prejudice by the Company. The Company will defend the lawsuit vigorously. The Company is unable to estimate the possible loss or range of loss, if any, associated with this lawsuit.

Note 12. Warrant Dividend Distribution

On January 3, 2024, the Company made a distribution to the holders of record of the Company's common stock in the form of warrants to purchase shares of common stock. Each holder of record of the Company's common stock as of the close of business on December 22, 2023 received four warrants for every 10 shares of common stock (rounded down for any fractional warrant) resulting in the issuance of approximately 16.9 million warrants.

Each warrant entitled the holder to purchase, at the holder's sole expense and exclusive election, at an exercise price of $33.00 per warrant, one and one-half shares of common stock (rounded down for any fractional shares). Payment for shares of common stock upon exercise of warrants was required to be in cash.

On April 15, 2024, the Company announced that all outstanding warrants would be redeemed on May 7, 2024 (the "Redemption Date"). The redemption price was equal to 1/10 of $0.01 per warrant. The warrants were exercisable at any time starting on January 3, 2024 until the business day prior to the Redemption Date. There are no remaining warrants currently outstanding.

The warrants were subject to the terms and conditions of the Warrant Agreement (including Form of Warrant), dated January 3, 2024, between Cassava Sciences, Inc., Computershare Inc., and Computershare Trust Company, N.A. as filed in a Current Report on Form 8-K with the SEC on January 3, 2024. The warrants were listed and traded separately from the Company's common stock on the Nasdaq Capital Market under the ticker "SAVAW".

From January 3, 2024 to March 31, 2024, a total of approximately 674,000 warrants were exercised resulting in net proceeds to the Company of approximately $22.3 million. The Company issued approximately 1.0 million shares of common stock from the exercise of warrants through March 31, 2024.

Subsequent to March 31, 2024 and through the Redemption Date, a total of approximately 3.15 million warrants were exercised resulting in gross proceeds to the Company of approximately $104.0 million. The Company issued approximately 4.7 million shares of common stock from the exercise of warrants from March 31, 2024 through the Redemption Date.

Gross proceeds in 2024 from the warrant distribution totaled approximately $126.3 million from the issuance of approximately 5.7 million common shares at $22.00 per share. Total net proceeds of the warrant distribution were approximately $123.6 million after deducting estimated exercise expenses.

After the first $20 million of gross proceeds, the Company was obligated to pay a commission of 2.5% of the gross proceeds from the sale of shares of common stock from warrant exercises to the Company's financial advisor for the warrant distribution. Total cost of warrant exercises through the Redemption Date were approximately $2.7 million.

Costs of the warrant distribution totaling approximately $537,000 were recorded as general and administrative expenses in the statements of operations upon distribution of the warrants on January 3, 2024.

The outstanding warrants are classified as liabilities in accordance with ASC 480 and ASC 815, which requires the warrants to be measured at initial fair value on January 3, 2024 and at each reporting period thereafter, with the changes in fair value recognized as a non-cash gain or loss in our consolidated statements of operations.

During the period from common stock warrant distribution on January 3, 2024 to the Redemption Date, changes in the Company's common stock warrants liability and warrants outstanding were as follows (in thousands):

	Number of Common Stock Warrants	Common Stock Warrant Liability
Distribution of common stock warrants on January 3, 2024	16,895	$ 113,363
Warrants exercised	(674)	(4,954)
Gain from change in fair value of warrant liabilities	—	(43,041)
Balance at March 31, 2024	16,221	65,368
Warrants exercised	(3,152)	(226)
Gain from change in fair value of warrant liabilities	—	(65,142)
Redemption of common stock warrants	(13,069)	—
Balance as of June 30, 2024	—	$ —

See Note 2 for additional information regarding common stock warrants and associated warrant liability.

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 consolidated 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.

Forward-looking Statements and Notices

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:

- the expected safety profile or treatment benefits, if any, of simufilam for people with Alzheimer's disease in our on-going Phase 3 studies;
- our reliance on third-party contractors to conduct all of our clinical and non-clinical trials and 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;
- our ability to extend our 1-year open-label extension study for an additional period of time;
- limitations around data interpretation from results of any of the three clinical phases of our 2-year safety study of simufilam in patients with Alzheimer's disease, as compared to clinical results from randomized controlled trials;
- the ability of clinical scales to assess cognition or health in our trials of Alzheimer's disease;
- any significant changes we may make, or anticipate making, to the design of any of our on-going Phase 3 studies of simufilam in patients with Alzheimer's disease;
- 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 impact of pre-clinical findings on our ability to develop our product candidates;
- the interpretation of results from our pre-clinical or early clinical studies, such as Phase 1 and Phase 2 studies;
- our plans to further develop SavaDx, our investigational blood-based diagnostic product candidate;
- our ability or willingness to expand therapeutic indications for simufilam outside of Alzheimer's disease;
- the safety, efficacy, or potential therapeutic benefits of our product candidates;
- our use of exploratory 'research use only' non-safety related biomarkers in our clinical studies;
- our ability to file for and obtain regulatory approval of our product candidates;
- our strategy and ability to establish an infrastructure to commercialize any product candidates, if approved;
- the potential future revenues of our product candidates, if approved and commercialized;
- the market acceptance of our product candidates, if approved and commercialized;
- the pricing and reimbursement of our product candidates, if approved and commercialized;
- the utility of protection, or the sufficiency, of our intellectual property;
- our potential competitors or competitive products for the treatment of Alzheimer's disease;
- our need to raise new capital from time to time to continue our operations or to expand our operations;

- our use of multiple third-party vendors and collaborators, including a Clinical Research Organization ("CRO"), to conduct clinical and non-clinical studies of our lead product candidate;
- expectations regarding trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions;
- our expenses or incurred costs increasing by material amounts in excess of budgeted amounts due to unexpected cost overruns, inflation, imperfect forecasting, increased scope of activities or other causes;
- fluctuations in our financial or operating results;
- our operating losses, anticipated operating and capital expenditures and legal expenses;
- expectations regarding the issuance of shares of common stock, options or other equity to employees or directors pursuant to equity compensation awards, net of employment taxes;
- the development and maintenance of our internal information systems and infrastructure;
- our ability to minimize the likelihood and impact of adverse cybersecurity incidents in our information systems and infrastructure;
- our need to hire additional personnel and our ability to attract and retain such personnel;
- existing or emerging regulations and regulatory developments in the United States and other jurisdictions in which we operate;
- our plans to expand the size and scope of our operations;
- the sufficiency of our cash resources to continue to fund our operations;
- potential future agreements with third parties in connection with the commercialization of our product candidates;
- the accuracy of our estimates regarding expenses, loss contingency reserves, capital requirements, and needs for additional financing;
- assumptions and estimates used for our disclosures regarding stock-based compensation;
- the expense, timing and outcome of pending or future litigation or other legal proceedings and claims, including U.S. government inquiries and their potential resolution; and
- litigation, claims or other uncertainties that may arise from allegations made against us or our former employees or collaborators.

Please also refer to the section entitled “Risk Factors” in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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.

This Quarterly Report on Form 10-Q may also contain statistical data and drug information received from our independent consultants or based on industry publications or other publicly available information. We have not independently verified the accuracy or completeness of the data contained in these sources of data and information. Accordingly, we make no representations as to the accuracy or completeness of such data and information. You are cautioned not to give undue weight to such data and information.

Our research programs in neurodegeneration have historically benefited from 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, the Department of Health and Human Services, or any other agency of the United States government, or any of our vendors, collaborators or unrelated third-parties.

Overview

Cassava Sciences, Inc. is a clinical-stage biotechnology company based in Austin, Texas. 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 Alzheimer's brain. Our lead therapeutic drug candidate, simufilam, is under clinical evaluation for the proposed treatment of Alzheimer's disease dementia in Phase 3 clinical studies.

For over 12 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—a degenerative disease of the brain, where a patient's cognition and health functions decline over time as the disease progresses and the patient moves from mild to moderate to, eventually, severe Alzheimer's disease.

We currently have two biopharmaceutical assets under development:

- our lead therapeutic product candidate, called simufilam, is a novel oral treatment for Alzheimer's disease dementia; 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.

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

Our lead product candidate, simufilam, is a proprietary small molecule drug. Simufilam was discovered and designed in-house and was characterized by our academic collaborators during research activities that were conducted from approximately 2008 to date.

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. Specifically, we believe simufilam disrupts amyloid binding to the α7 nicotinic acetylcholine receptor (α7nAChR), which underlies our drug's primary mechanism of action in Alzheimer's disease. More recent data also suggest a meaningful impact of simufilam on mTOR signaling. Because mTOR contributes to age-related cellular changes, simufilam's suppression of mTOR overactivation, concurrent with improved insulin sensitivity, may slow certain aging processes and attenuate this pathological feature, potentially benefiting brain function and memory in Alzheimer's disease and in aging.

We own exclusive, worldwide rights to our drug and diagnostic 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 diseases currently runs through 2039 and includes nine issued U.S. patents. Corresponding foreign filings have been made for each of the U.S. filings.

We are currently conducting two randomized placebo-controlled Phase 3 clinical trials of oral simufilam in patients with mild-to-moderate Alzheimer's disease dementia. Both trials are fully enrolled. The trials have randomized a total of approximately 1,900 patients with mild-to-moderate Alzheimer's disease at baseline. All efficacy data from our Phase 3 program remain blinded. There are no interim analyses on efficacy outcomes.

Our first Phase 3 study, called RETHINK-ALZ, is designed to evaluate the safety and efficacy of simufilam 100 mg tablets versus placebo over 52 weeks (NCT04994483). Top-line results of our 52-week Phase 3 study are anticipated by the end of 2024.

Our second Phase 3 study, called REFOCUS-ALZ, is designed to evaluate the safety and efficacy of oral simufilam 100 mg and 50 mg tablets versus placebo over 76 weeks (NCT05026177). Top-line results of our 76-week Phase 3 study are anticipated approximately mid-year 2025.

Phase 3 data and samples for bioanalysis will be directly provided to and analyzed by independent, third-party commercial consulting firms.

Business Update

Indictment of Dr. Hoau-Yan Wang

On June 28, 2024, the DOJ announced that a federal grand jury in the U.S. District Court for the District of Maryland returned an indictment of Dr. Wang. The indictment alleges that Dr. Wang caused Cassava to submit grant applications to the U.S. National Institutes of Health ("NIH") that contained false and fraudulent representations about his research. Among other things, the indictment alleges that Dr. Wang made materially false, fraudulent, and misleading statements to NIH regarding the mechanism by which the Company's therapeutic product candidate, simufilam, was designed to treat Alzheimer's disease and the improvement of certain Alzheimer's disease indicators in patients treated with simufilam, and that Dr. Wang manipulated or otherwise fabricated research results, including Western Blot images that he prepared.

Dr. Wang, who is employed as a professor at the School of Medicine of the City University of New York ("CUNY"), previously served as a scientific collaborator and advisor to Cassava. Dr. Wang's research, including foundational research published together with Dr. Lindsay Burns, Cassava's former SVP, Neuroscience, led to the discovery of simufilam. Among other work for Cassava, Dr. Wang's laboratory at CUNY conducted the final bioanalysis for the Phase 2b Study, which the Company reported as part of the final results of the Phase 2b Study.

Dr. Wang received compensation from the Company for his consulting and advisory work for Cassava. For over a decade until Cassava's termination of its consulting relationship with him, Dr. Wang was paid a cash stipend of $2,000 per month. He has also been awarded stock options pursuant to the Company's equity incentive plans, none of which have been exercised through August 5, 2024. As of August 5, 2024, Dr. Wang held 18,571 stock options, all of which were granted between 2015 and 2019 and are fully vested, with a weighted average exercise price of $4.22 per share. Dr. Wang was previously a participant in the Company's CIB Plan, during which time the Company achieved target valuation milestones that established aggregate bonus payment amounts. The determination whether to award such amounts to participants and, if so, the allocation of amounts among participants (other than the Company's chief executive officer), has not yet occurred and remains subject to the discretion of the Compensation Committee of the Board. In all cases, the payment of cash bonuses under the CIB Plan is subject to (i) Cassava's completion of a merger transaction or (2) the determination by the Compensation Committee of the Board that the Company has sufficient cash on hand to render such payment, neither of which may ever occur. To date, Dr. Wang has not been allocated any cash bonus award pursuant to the CIB Plan. The Company has not paid any cash bonus to Dr. Wang or to any other participant under the CIB Plan as of this Quarterly Report on Form 10-Q. Prior to Dr. Wang's indictment, the Company terminated its consulting relationship with him, and the Board removed him as a participant in the CIB Plan.

Neither Dr. Wang nor his laboratory at CUNY has had any involvement at any time in the Company's ongoing Phase 3 clinical trials of simufilam.

Lawsuit Against Perpetrators of "Short and Distort" Campaign

On November 3, 2022, we announced that we had filed a lawsuit in federal district court for the Southern District of New York against certain individuals who executed a "short and distort" campaign against Cassava Sciences. On March 29, 2024, the court dismissed our complaint, but provided leave for the Company to file an amended complaint against certain defendants whom the Court found had published defamatory statements about the Company. The Company filed its Second Amended Complaint against these defendants on April 29, 2024. On August 2, 2024, the Company voluntarily dismissed its claims against the defendants named in the Second Amended Complaint without prejudice.

Leadership Updates

Appointment of Executive Chairman of the Board of Directors

On July 15, 2024, Richard J. Barry, an independent director, was appointed by the Board as its Executive Chairman. Mr. Barry will serve as the Company's principal executive officer until a permanent Chief Executive Officer is identified.

Mr. Barry, 65, has served as a director since June 2021. Since June 2015, Mr. Barry has served as a director of Sarepta Therapeutics, Inc. (Nasdaq: SRPT) and from June 2019 through October 2020, he served as a director of MiMedx Group Inc. (Nasdaq: MDXG). Mr. Barry has extensive experience in the investment management business. He was a founding member of Eastbourne Capital Management LLC, and served as a Managing General Partner and Portfolio Manager from 1999 to its close in 2010. Prior to Eastbourne, Mr. Barry was a Portfolio Manager and Managing Director of Robertson Stephens Investment Management. Mr. Barry holds a Bachelor of Arts from Pennsylvania State University. The Board has concluded that Mr. Barry's experience as founder and managing director of investment funds and as a director to public companies, including service on Audit, Compensation, and Nominating and Governance Committees, qualifies him to serve as Executive Chairman.

Resignation of Chief Executive Office and Chairman of the Board of Directors

On July 15, 2024, Remi Barbier, President and Chief Executive Officer of the Company resigned from the Company, effective as of September 13, 2024 (the "Effective Date"). Mr. Barbier will remain employed by the Company through the Effective Date in a non-executive capacity, without duties or responsibilities. Pursuant to the terms of Mr. Barbier's Employment Agreement, Mr. Barbier will receive severance compensation equal to $1.23 million over twelve months following the Effective Date, together with accrued salary through the Effective Date. Mr. Barbier will continue to participate in the Company's medical plan at Cassava's expense and will receive a payment sufficient to provide insurance coverage equivalent to existing third-party plans, in each case for a period of twelve months following separation. In addition, on July 15, 2024, the Company's Board accepted Mr. Barbier's resignation as Chairman of the Board and from board membership, effective on that date.

Other Management Changes

On July 16, 2024, Cassava and Lindsay Burns, Ph.D., SVP, Neuroscience, at the Company, agreed that Dr. Burns would step down from her employment with the Company, effective on that date.

The terms of Dr. Burns' separation are set forth in a Consulting Agreement (the "Burns Agreement"), which includes a Release Agreement, between Dr. Burns and the Company, dated July 16, 2024. Pursuant to the Burns Agreement, following her separation from the Company and for a one-year period, Dr. Burns will furnish consulting services as, and to the extent, reasonably requested by Cassava for purposes of providing information and support for scientific research and/or obtaining governmental approval for the Company's products. Cassava may, in its sole discretion, extend the term of the Burns Agreement for up to an additional year. The Company may also terminate the Burns Agreement at any time for cause, including, without limitation, for any actions that discredit Cassava's business reputation. Dr. Burns will be paid $500 per hour for such consulting services, which will constitute continuous service for purposes of outstanding equity awards held by Dr. Burns.

Pursuant to the Burns Agreement, Dr. Burns will receive severance compensation equal to $0.5 million in quarterly installments over twelve months, together with accrued salary through July 16, 2024. Dr. Burns will continue to participate in the Company's medical plan at Cassava's expense for a period of twelve months following separation, which may be extended to eighteen months in connection with an extension of the term of the Burns Agreement. Dr. Burns will remain eligible for applicable indemnification rights under Dr. Burns' existing indemnification agreement, the Company's by-laws and the Company's insurance policies, in each case, subject to the terms and conditions and limitations thereof.

The Burns Agreement provides for Dr. Burns' general release of claims in favor of the Company, subject to certain exceptions. In addition, Dr. Burns is subject to a one-year non-competition covenant, a two-year non-solicitation covenant, and indefinite non-disparagement and confidentiality covenants. Dr. Burns will remain subject to her existing assignment of inventions agreement.

Risk is Fundamental to the Drug Development Process

We are in the business of new drug discovery and development. Our research and development activities are long, complex, costly and involve a high degree of risk. Holders of our common stock should carefully read this Quarterly Report on Form 10-Q as well as our 2023 Annual Report on Form 10-K in its entirety, including "Item 1A. Risk Factors". *Because risk is fundamental to the process of drug discovery and development, you are cautioned to not invest in our publicly traded securities unless you are prepared to sustain a total loss of the money you have invested.*

About Alzheimer's Disease

Alzheimer's is a degenerative disease of the brain that affects cognition, function and behavior. Over time, a patient's cognition and health functions decline as the disease takes its toll. With disease progression, patients move from mild to moderate to, eventually, severe Alzheimer's disease. Cognitive decline becomes more pronounced, and presumably more difficult to treat, in advanced stages of the disease.

An estimated 6.7 million Americans age 65 and older were living with Alzheimer's dementia in 2023, according to the Alzheimer's Association. According to the same source, in 2011, the largest ever demographic generation of the American population — the baby-boom generation — started reaching age 65. By 2030, the segment of the U.S. population age 65 and older will have grown substantially, and the projected 74 million older Americans will make up over 20% of the total population. Because age is a well-known risk factor for Alzheimer's dementia, new cases of Alzheimer's dementia are expected to climb with the growth in the number of elderly Americans.

Our Scientific Approach is Different

Given the biopharmaceutical industry's challenging track record in Alzheimer's research and drug development, we believe there is an urgent need to consider innovative approaches to combat this disease.

For more than twelve years, we have developed a new and promising scientific approach for the treatment and diagnosis of neurodegenerative diseases, such as Alzheimer's disease. Importantly, we do not seek to clear amyloid out of the brain. Rather, our novel science is based on stabilizing – but not removing – a critical protein in the brain.

Our scientific approach is to treat neurodegeneration by targeting an altered form of a scaffold protein called FLNA. Through years of basic research, we and our academic collaborators identified FLNA as a structurally altered protein that enables neurodegeneration and neuroinflammation pathways in the Alzheimer's brain. We have shown that the altered form of FLNA is pervasive in the Alzheimer's brain and essentially undetectable in healthy control brains.

Using scientific insight and lab techniques, we believe we have elucidated this protein dysfunction. Through this work, we have produced experimental evidence that altered FLNA plays a critical role in Alzheimer's disease. We engineered a family of high-affinity, small molecules to target this structurally altered protein and restore its normal shape and function. This family of small molecules, including our lead therapeutic product candidate, simufilam, was designed in-house and characterized by our academic collaborators.

Our lead drug candidate, simufilam, is a small molecule (oral) drug with a novel mechanism of action. The target of simufilam is altered FLNA, the structurally altered protein in the brain that we seek to stabilize. Importantly, since simufilam has a unique mechanism of action, we believe its potential therapeutic effects may be additive or synergistic with existing drug treatments for Alzheimer's disease dementia.

Our science is based on stabilizing a critical protein in the brain

Proteins are essential for cell function because they participate in virtually every biological process. If protein function is impaired, the health consequences can be devastating. Technological advances in medicine and improvements in lifestyle are making our lives longer. But with age, genetic mutations and other factors conspire against healthy cells, resulting in altered proteins. Sometimes a cell can rid itself of altered proteins. However, when disease changes the shape and function of critical proteins, multiple downstream processes are impaired. There are many clinical conditions in which proteins become structurally altered and impair the normal function of cells, tissues and organs, leading to disease. Conversely, restoring altered proteins back to health –called proteostasis – is a well-accepted therapeutic strategy in clinical medicine.

For over 100 years, scientists have ascribed various neurodegenerative diseases to proteins that misfold and are rendered pathological. In Alzheimer's disease, certain proteins, such as amyloid and tau, lose their normal shape and function. Such misfolded proteins can break down or aggregate in clumps and form plaque or tangles in the brain. Destruction of neuronal synapses, accelerated death of neurons, and dysfunction of the brain support cells, are all widely believed to be direct consequences of misfolded proteins.

FLNA is a scaffolding protein found in high levels in the brain. A healthy scaffolding protein brings multiple proteins together, coordinating their interaction. However, an altered form of FLNA protein is found in the Alzheimer's brain. Our experimental evidence shows that altered FLNA protein contributes to Alzheimer's disease by disrupting the normal function of neurons, leading to neurodegeneration and brain inflammation. Our product candidate, simufilam, aims to counter the altered and toxic form of FLNA in the brain, thus restoring the normal function of this critical protein.

One drug, multiple effects

Simufilam binds to altered FLNA with very high (femtomolar) affinity. We believe simufilam improves brain health by reverting altered FLNA back to its native, healthy conformation, thus countering downstream toxic effects of altered FLNA. This drug effect restores the normal function of key brain receptors, including: the alpha-7 nicotinic acetylcholine receptor; the N-methyl-D-aspartate (NMDA) receptor; and the insulin receptor. These receptors have pivotal roles in brain cell survival, cognition and memory. In addition, recent data suggest a beneficial impact of simufilam on mTOR signaling.

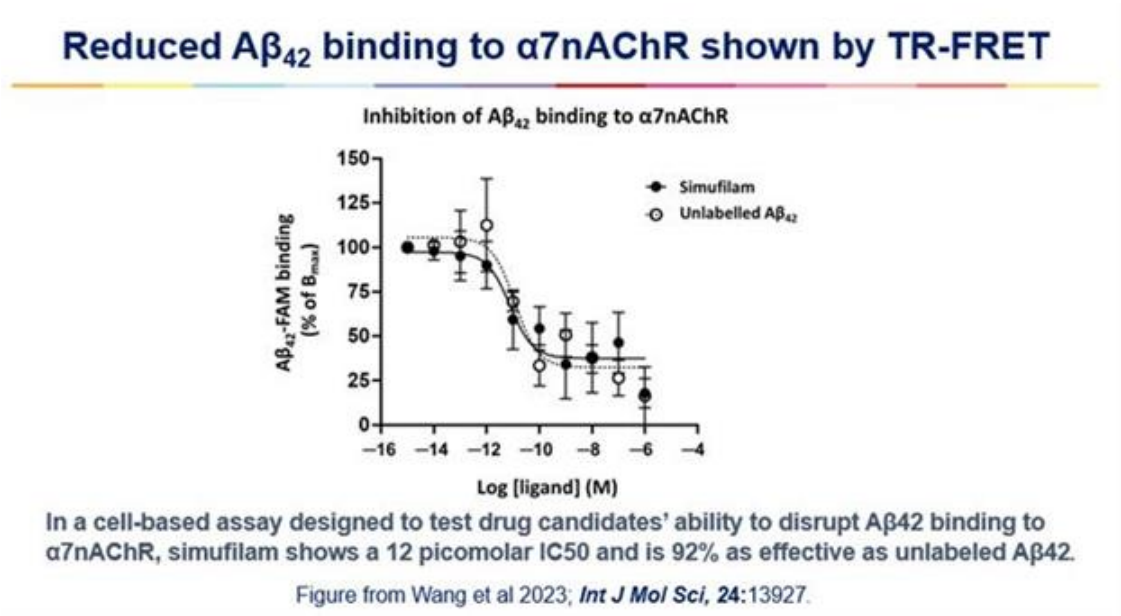
We have generated and published experimental evidence of improved brain health by restoring altered FLNA with simufilam. In animal models, treatment with simufilam resulted in dramatic improvements in brain health, such as reduced amyloid and tau deposits, improved receptor signaling and improved learning and memory. In addition, simufilam has another beneficial treatment effect of significantly reducing inflammatory cytokines in the brain. In animal models of disease, treatment with simufilam greatly reduced levels of IL-6 and suppressed TNF-alpha and IL-1beta levels by 86% and 80%, respectively, illustrating a powerful anti-neuroinflammatory effect.

By restoring function to multiple receptors and exerting powerful anti-inflammatory effects, we believe our approach has potential to slow the progression of Alzheimer's disease in patients. We also believe our scientific approach may broaden the range of possible treatment approaches for this complex disease.

Publication Confirming Mechanism of Action of Simufilam

In September 2023, we announced the publication of new research that confirms the biological activity of simufilam. Researchers at the Cochin Institute (Paris, France) used a highly precise cell-based assay based on TR-FRET to show that simufilam interrupts amyloid binding to the α7 nicotinic acetylcholine receptor (α7nAChR). We believe disruption of amyloid binding to α7nAChR underlies simufilam's primary mechanism of action in Alzheimer's disease. The research paper was co-authored by Hoau-Yan Wang and Zhe Pei of the City University of New York, Erika Cecon, Julie Dam and Ralf Jockers of the Institut Cochin, and Lindsay Burns, a former employee of Cassava Sciences, and appeared in a special issue of *International Journal of Molecular Sciences,* a peer-reviewed journal. See Figure 1.

Figure 1. Experiment conducted by Erika Cecon, Université Paris Cité, Institut Cochin in an assay she developed: Cecon et al 2019; *Br J Pharmacol;* 176:3475-3488. Data shown are means of pooled data from 4 separate experiments ±SEM.



Publication Showing Simufilam Suppresses Overactive mTOR

In June 2023, we announced the publication of new research that showed the effects of simufilam on the mechanistic Target of Rapamycin (mTOR). Scientific literature shows overactive mTOR plays a key role in aging, Alzheimer's disease and other conditions. When functioning normally, mTOR monitors cellular needs and is activated by insulin. The new published research shows mTOR is overactive in lymphocytes isolated from blood collected from Alzheimer's patients versus healthy controls. After oral administration of simufilam 100 mg twice daily to Alzheimer's patients for 28 days, lymphocytes showed normalized mTOR activity and restored sensitivity to insulin.

These data suggest a meaningful impact of simufilam on mTOR signaling. The suppression of overactive mTOR signaling and its improved responsiveness to insulin represents a mechanistic benefit of simufilam beyond the disruption of pathogenic signaling pathways of soluble amyloid. These improvements in mTOR signaling may also result from reversing an altered conformation of FLNA, allowing FLNA to dissociate from the insulin receptor when insulin binds and initiates signaling. Because mTOR contributes to age-related cellular changes, simufilam's suppression of mTOR overactivation, concurrent with improved insulin sensitivity, may slow certain aging processes and attenuate this pathological feature of Alzheimer's disease, potentially benefiting brain function and memory in Alzheimer's disease and in aging. This mTOR research paper was co-authored by Hoau-Yan Wang, Zhe Pei and Kuo-Chieh Lee of the City University of New York, Boris Nikolov, Tamara Doehner and John Puente, who are investigators in the clinical trial protocols, and Lindsay Burns, a former employee of Cassava Sciences, and appeared in *Frontiers in Aging*, a peer-reviewed journal.

Simufilam Drug Development

IND submission to FDA, Drug Safety in Early Clinical Studies

For over a decade, we conducted basic research, in vitro studies and preclinical studies in support of a successful Investigational New Drug (IND) submission to FDA for simufilam, including requisite studies around safety pharmacology, toxicology, genotoxicity and bioanalytical methods. In 2017 we filed an IND with FDA for simufilam.

Following FDA acceptance of our IND in 2017, we investigated the safety, dosing and pharmacokinetic profile of simufilam in healthy human volunteers. The design of our first-in-human Phase 1 study was based on regulatory feedback, clinical and scientific rationale and observations from previously conducted preclinical and in vitro studies. In a Phase 1 study, simufilam was evaluated in 24 healthy human volunteers (18 simufilam, 6 placebo) in a single site in the U.S. for safety, tolerability and pharmacokinetics. Study subjects were administered a single oral dose of 50, 100 or 200 mg of simufilam or placebo. Drug appeared safe and well-tolerated. Importantly, simufilam showed no treatment-related adverse effects and no dose-limiting safety findings. Pharmacokinetic measurements demonstrated that simufilam, a small molecule, was rapidly absorbed. Dose-proportionality was observed over the full dose range of 50 to 200 mg.

24-Month Clinical Safety Study

Much of the strategic value of our 24 month clinical safety study is to support simufilam's long-term safety profile in patients. We believe a well-designed, long-term, safety study is a prudent risk-management undertaking. Clinical results may serve to help inform and manage the inherent risks and uncertainties of drug development while we undertake a large, expensive Phase 3 clinical testing program.

In March 2020, we initiated a clinical safety study of simufilam, our lead drug candidate, in patients with Alzheimer's disease (NCT04388254). This study was funded in part by a research grant award from NIH. This study was designed to evaluate the long-term clinical safety and tolerability of simufilam in patients with Alzheimer's disease over 24 months. The study included a pre-specified exploratory efficacy endpoint of mean change in ADAS-Cog11 scores, a cognitive scale widely used in Alzheimer's clinical research. This study enrolled over 200 patients with mild-to-moderate Alzheimer's disease (Mini-Mental State Examination (MMSE) 16-26) who were recruited from 16 U.S. clinical sites. Alzheimer's is a progressive disease, with severity of disease typically assessed by MMSE score. In this study, mild patients are MMSE 21-26, and moderate patients are MMSE 16-20.

We conducted the 24-month safety study in three continuous phases:

- a 12-month, open-label treatment phase, followed by
- a 6-month randomized, placebo-controlled withdrawal phase (previously referred to as the "Cognition Maintenance Study" or CMS), followed by
- 6 additional months of open-label treatment.

Study participants received simufilam oral tablets 100 mg twice-daily in the open-label treatment phases, and simufilam or matching placebo during the randomized withdrawal phase. In an open-label study design, both the health providers and the patients are aware of the drug treatment being given.

All study participants who completed 12 months of open-label simufilam treatment were eligible to participate in the 6-month randomized, placebo-controlled withdrawal phase. Likewise, all study participants who completed the randomized, placebo-controlled withdrawal phase were eligible for 6 additional months of open-label treatment.

Study Results for the 12-month, Open-label Treatment Phase

In January 2023, we announced positive top-line results for the 12-month, open-label treatment phase of the safety study. The pre-specified, exploratory efficacy endpoint was change in baseline on ADAS-Cog11, a cognitive scale widely used in Alzheimer's clinical research. Other exploratory endpoints included the Mini-Mental State Examination (MMSE) to assess disease stage by cognitive impairment; the Neuropsychiatric Inventory (NPI) to assess dementia related behavior; and the Geriatric Depression Scale (GDS). Endpoints were measured at baseline (study entry) and month 12.

Top-line Results – mean scores, baseline to month 12 (*lower is better, except for MMSE)***:**

- ADAS-Cog11 scores changed from 19.1 (±9.2) to 19.6 (±13.3)
- MMSE scores changed from 21.5 (±3.6) to 20.2 (±6.4)
- NPI10 scores changed from 3.2 (±4.6) to 2.9 (±4.6)
- GDS scores changed from 1.8 (±1.8) to 1.4 (±1.9)

Response Analysis – baseline to month 12

- ADAS-Cog scores improved in 47% of patients; this group had a mean change of -4.7 (±3.8) points (lower is better).
- In an additional 23% of patients, ADAS-Cog declined less than 5 points; this group had a mean change of 2.5 (±1.4) points.
- Patients with an NPI10 score of zero increased from 42% to 54%, indicating reduced dementia-related neuropsychiatric symptoms after 1 year on simufilam.

The Full Analysis Set (FAS) population (N=216) was used for the statistical analysis of efficacy endpoints.

Mild and moderate sub-groups showed notable differences on changes in ADAS-Cog mean scores, baseline to month 12 (lower is better):

- In the *mild* sub-group (MMSE 21-26), mean ADAS-Cog scores improved, from 15.0 (±6.3) to 12.6 (±7.8)
- In the *moderate* sub-group (MMSE 16-20), mean ADAS-Cog scores worsened, from 25.7 (±9.2) to 30.1 (±13.1)

We believe the improvement in ADAS-Cog over 1 year in mild patients taking simufilam is well outside the expected range of historic placebo decline rates from numerous other studies. Figure 2: historical declines on ADAS-Cog in early disease (MCI + mild) and mild disease.

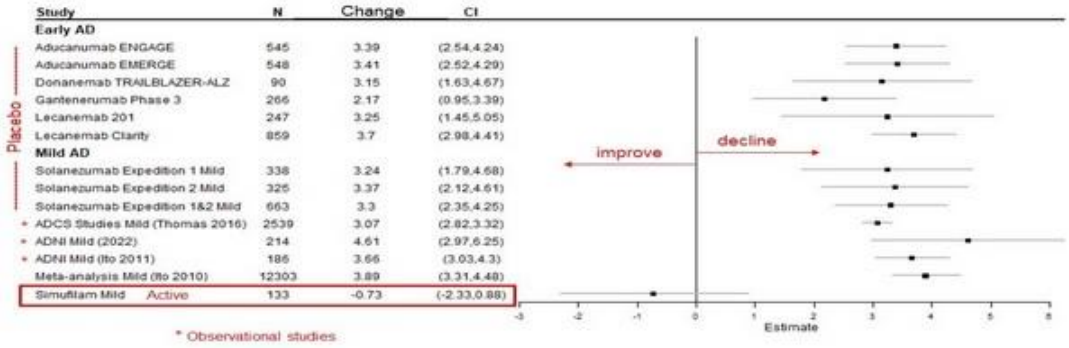


Figure 1: *Statistical model of simufilam versus historical 1-year placebo declines on ADAS-Cog in early disease and mild disease. Forest plot by Pentara Corporation, independent biostatisticians. Data was sourced from non-randomized studies (i.e., ADNI) and randomized, controlled trials conducted by other sponsors in patients with early (i.e., MCI + mild) and mild Alzheimer's disease.*

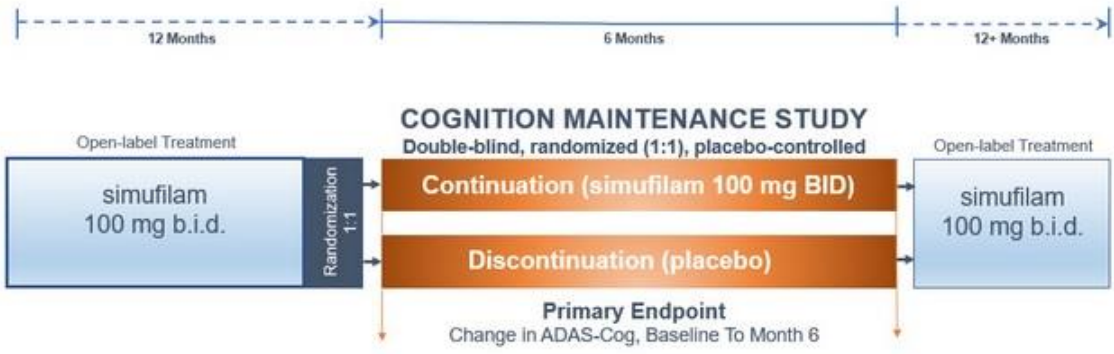
Safety Data - Simufilam 100 mg tablets twice daily appeared safe and well tolerated in this treatment phase of the open-label study. There were no drug-related serious adverse events. Three treatment-emergent adverse events (TEAEs) occurred in 7% or more of study patients: COVID-19 (12%), urinary tract infection (10%) and headache (9%). Reported TEAEs are based on all study patients who received at least one dose of drug.

Study Results for the 6-month, Randomized Withdrawal Study Phase ("Cognition Maintenance Study")

In May 2021, we initiated the randomized, withdrawal phase of the 24 month safety study, which has been previously referred to as the 'Cognition Maintenance Study' or CMS. The CMS has a randomized, withdrawal study design. The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) explains that in a randomized withdrawal study, "*subjects receiving a test treatment for a specified time are randomly assigned to continued treatment with the test treatment or to placebo (i.e., withdrawal of active therapy) … Any difference that emerges between the group receiving continued treatment and the group randomized to placebo would demonstrate the effect of the active treatment*."

The design of the randomized, withdrawal phase of the study was intended to evaluate simufilam's effects on cognition and health outcomes in Alzheimer's patients who continue with drug treatment versus patients who discontinue drug treatment. This was a double-blind, randomized, placebo-controlled study of simufilam in patients with mild-to-moderate Alzheimer's disease. Study patients were randomized (1:1) to simufilam or placebo for six months. To enroll in the CMS, patients must have previously completed 12 months or more of open-label treatment with simufilam. Final enrollment was 157 patients. See Figure 3.

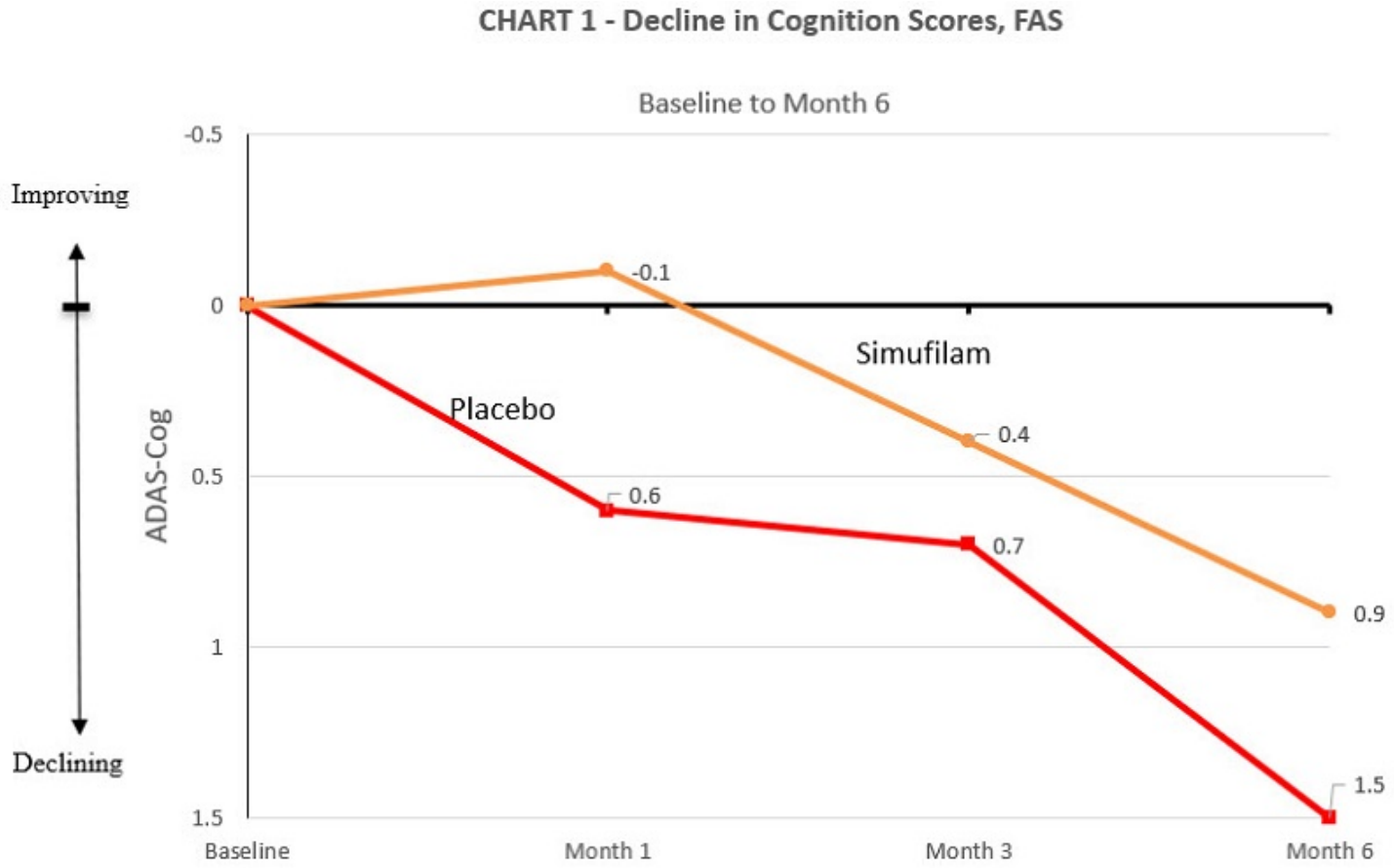
Figure 3. Design of the Randomized Withdrawal Phase (CMS)



Top-line Results - Simufilam treatment for 6 months slowed cognitive decline by 38% compared to placebo in mild-to-moderate Alzheimer's disease (MMSE 16-26) patients. The placebo arm declined 1.5 points on ADAS-Cog, and this arm declined at all measured timepoints. The simufilam arm declined 0.9 points on ADAS-Cog, a 38% difference in favor of drug at month 6 (95% CI, – 2.1 to 1.0; not significant for sample sizes). See Table 1 and Chart 1.

Table 1: Results of Randomized Withdrawal Study – cognitive change, full analysis set (FAS)

Full Analysis Set	**Simufilam 100 mg (N = 78)**	**Placebo (N = 77)**	**Numerical Difference**	**Percent Difference**
6-month Change in ADAS-Cog	0.9 point Decline	1.5 point Decline	–0.6	38% in favor of drug

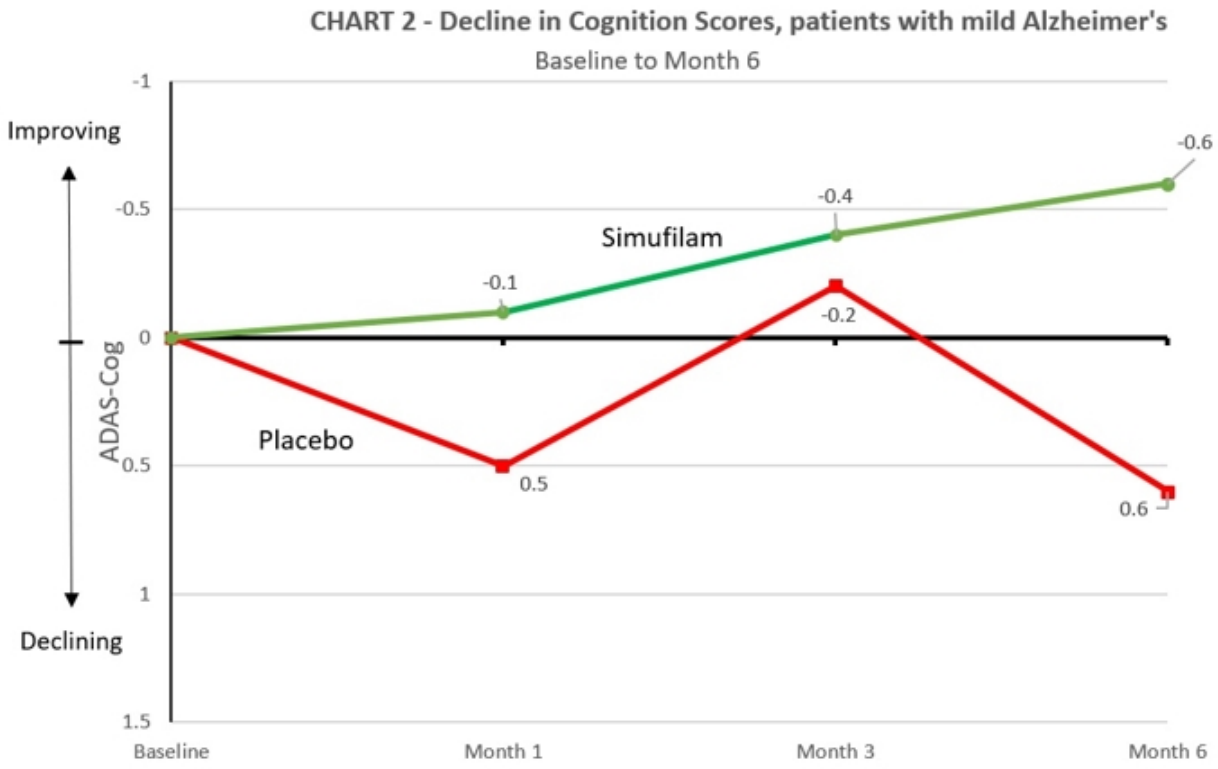


Upon randomization into the randomized, withdrawal phase, mean baseline MMSE scores were 18.6 and 18.1 for the simufilam and placebo arms, respectively. Mean baseline ADAS-Cog scores were 19.3 and 21.9 for the simufilam and placebo arms, respectively.

Simufilam Drug Effects Favored Patients with Mild Alzheimer's Disease – Simufilam treatment for 6 months slowed cognitive decline > 200% compared to placebo in mild Alzheimer's disease. Patients with mild Alzheimer's (MMSE 21-26) on placebo declined 0.6 points on ADAS-Cog over 6 months as a group. Patients with mild Alzheimer's on simufilam improved 0.6 points over 6 months as a group, a 205% difference in favor of drug (95% CI, – 2.6 to 0.4; not significant for sample sizes). See Table 2 and Chart 2.

Table 2: Results of Randomized Withdrawal Study – cognitive change, mild patients

Mild Patients	**Simufilam 100 mg (N= 40)**	**Placebo (N= 36)**	**Numerical Difference**	**Percent Difference**
6-month Changes in ADAS-Cog	0.6 point Improvement	0.6 point Decline	–1.1	205% in favor of drug



Upon randomization into the randomized, withdrawal phase of the study, mean baseline MMSE scores for mild patients were MMSE 24.0 and MMSE 24.1 for the simufilam and placebo arms, respectively. Mean baseline ADAS-Cog scores for mild patients were 11.0 and 11.2 for the simufilam and placebo arms, respectively.

Simufilam for 18 months stabilized cognition in mild Alzheimer's disease – After taking open-label simufilam for 12 months, 76 patients with mild Alzheimer's disease (MMSE 21-26) enrolled in the randomized, withdrawal phase and were randomized to receive either simufilam (N=40) or placebo (N=36) for 6 months. Mild patients randomized to simufilam in the CMS showed no material decline in ADAS-Cog scores over 18 months as a group, indicating stable cognition. Mild patients randomized to placebo in the randomized, withdrawal phase (and therefore withdrawn from simufilam treatment for 6 months) declined by 0.8 points in ADAS-Cog over 18 months as a group. See Figure 4.

Figure 4. Historical declines on ADAS-Cog over 18 months in Alzheimer's disease (MMSE 20-30), placebo arms vs simufilam treatment.

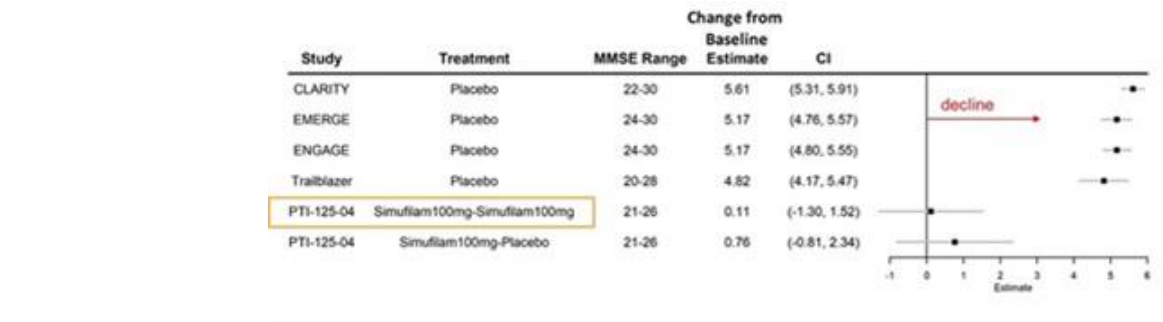


Figure 4: Forest plot by Pentara Corporation, independent biostatisticians. Data was sourced from the placebo groups in randomized, controlled trials of monoclonal antibodies conducted by other sponsors in Alzheimer's disease (MMSE 20-30). Results shown for CLARITY P3 trial of lecanemab; EMERGE and ENGAGE P3 studies of aducanumab; and TRAILBLAZER P3 trial of donanemab; in this figure, the randomized, withdrawal phase is referred to as the 'PTI-125-04' study; 'Simufilam100mg-Simufilam100mg' refers to patients who received simufilam in both the open-label phase and the randomized, withdrawal phase; 'Simufilam100mg-Placebo' refers to patients who received simufilam in the open-label phase and placebo in the randomized, withdrawal phase.

Safety Data – Simufilam 100 mg tablets twice daily appeared safe and well tolerated in the 6-month the randomized, withdrawal phase of the 24 month safety study.

Discussion – Patients who completed 12 months of open-label simufilam treatment were invited to participate in the randomized, withdrawal phase. It is not known how long a washout period may be needed to remove lingering drug effects, if any, from prior treatment with open-label simufilam for 12 months. In this small randomized, withdrawal study phase in patients with mild-to-moderate Alzheimer's disease, simufilam slowed cognitive decline by 38% on ADAS-Cog over six months (not statistically significant), with good drug safety. Effects were pronounced in mild patients. Mean baseline MMSE and ADAS-Cog scores were approximately balanced given the small size of each arm.

Study Results for the 24-Month Safety Study

In February 2024, we reported top-line results of the 24-month clinical safety study. Average changes in ADAS-Cog scores, baseline to month 24, indicate the following:

- Patients with mild Alzheimer's disease who received simufilam treatment continuously for two years (n=47) had no decline in ADAS-Cog scores (± 1.51 SE) as a group.
- Patients with mild Alzheimer's who received simufilam treatment non-continuously (n=40) declined 1 point on ADAS-Cog (± 1.65 SE) as a group. Non-continuous treatment consisted of one year on open-label drug, six months on placebo and six months back on open-label drug.
- In patients with mild Alzheimer's, the largest separation between the continuous and non-continuous treatment groups occurred at the end of the 6-month randomized, placebo-controlled withdrawal phase.
- Patients with moderate Alzheimer's who received simufilam treatment continuously for two years (n=32) declined 11.05 points on ADAS-Cog (± 1.91 SE) as a group.

Patients with mild Alzheimer's disease (n=87) started the 24 months study with MMSE 21-26, with ten exceptions (*i.e.,* patients with MMSE > 26 due to prior participation in a study of simufilam (n=2) or evidence of Alzheimer's disease pathology (n=8)). Patients with moderate Alzheimer's started the 24 months study with MMSE 16-20, with one patient who entered with MMSE 15.

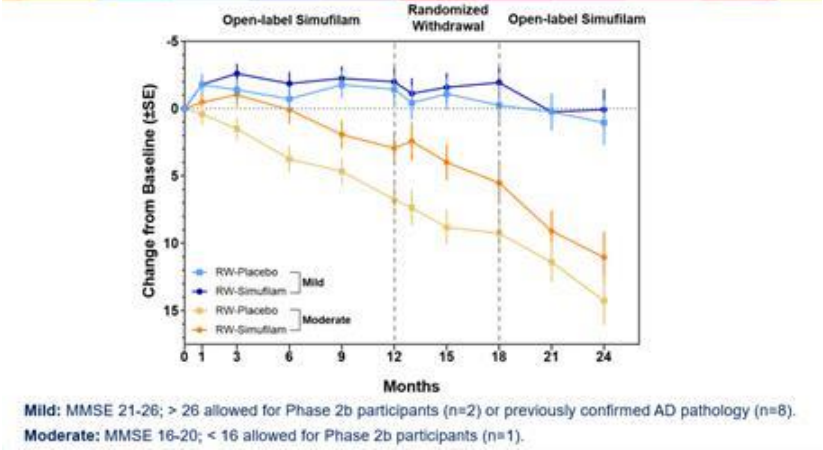
The pre-specified cognition endpoints were analyzed on the Full Analysis Set (FAS) by an independent consulting firm that specializes in complex statistical analysis of clinical trial results. The FAS population consists of all study participants who received at least one dose of treatment and have both baseline and at least one post-baseline assessment. (Because FAS data is specific to each phase of a study, the FAS for the 24-month study may differ from the FAS for other study phases).

Mild patients who received simufilam for 24 continuous months (n=47) showed an average change of 0.07 points on ADAS-Cog11 (± 1.51 SE), baseline to month 24, as a group.

Mild Alzheimer's patients who received 12 months of open-label simufilam, followed by placebo in the 6-month randomized, placebo-controlled withdrawal phase, followed by an additional 6 months of open-label simufilam (n=40), declined by an average of 1.04 points on ADAS-Cog11 (± 1.65 SE), baseline to month 24, as a group. See Figure 4B.

Figure 4

Change in ADAS-Cog11 in Mild vs. Moderate



Mild: MMSE 21-26; > 26 allowed for Phase 2b participants (n=2) or previously confirmed AD pathology (n=8).
Moderate: MMSE 16-20; < 16 allowed for Phase 2b participants (n=1).

Mean ADAS-Cog scores at baseline were approximately balanced in the group of mild Alzheimer's patients who received drug continuously versus non-continuously (15.2 and 14.6, respectively).

Safety Data – Oral simufilam 100 mg tablets twice daily appeared safe and well tolerated in this study. There were no drug-related serious adverse events. The most common treatment-emergent adverse events (TEAEs) were Covid-19 and urinary tract infection.

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 meeting 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 agreed that the completed Phase 2 program, together with an ongoing and well-defined Phase 3 clinical program, are sufficient to potentially show evidence of clinical efficacy for simufilam in Alzheimer's disease. There was also agreement that the use of separate clinical scales to assess cognition (ADAS-cog[1]) and function (ADCS-ADL[2]) are appropriate endpoints of efficacy. iADRS[3] is an efficacy endpoint that combines scores for ADAS-cog and ADCS-ADL, and thereby provide a single composite measure of cognition and health function. Other endpoints include the NPI[4].

[1] ADAS-Cog = The Alzheimer's Disease Assessment Scale – Cognitive Subscale, a measure of cognition

[2] ADCS-ADL = Alzheimer's Disease Cooperative Study – Activities of Daily Living, a measure of health function

[3]iADRS = integrated Alzheimer's Disease Rating Scale, a composite measure of cognition and health function

[4]NPI = Neuropsychiatric Inventory, a clinical tool that assesses the presence and severity of dementia-related behavior

Special Protocol Assessments

In August 2021, we announced we had reached agreement with FDA under a Special Protocol Assessment (SPA) for both Phase 3 studies. These SPA agreements document that FDA has reviewed and agreed upon the key design features of our Phase 3 study protocols of simufilam for the treatment of patients with Alzheimer's disease.

An SPA agreement indicates concurrence by the FDA with the adequacy and acceptability of specific critical elements of overall protocol design (e.g., entry criteria, dose selection, endpoints, etc.). These elements are critical to ensure that our planned Phase 3 studies of simufilam in Alzheimer's disease can potentially be considered adequate and well-controlled studies in support of a future regulatory submission and marketing application.

The first clinical study protocol under the SPA is titled "*A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 52-Week Study Evaluating the Safety and Efficacy of One Dose of Simufilam in Subjects with Mild-to-Moderate Alzheimer's Disease*."

The second clinical study protocol under the SPA is titled "*A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 76-Week Study Evaluating the Safety and Efficacy of Two Doses of Simufilam in Subjects with Mild-to-Moderate Alzheimer's Disease*."

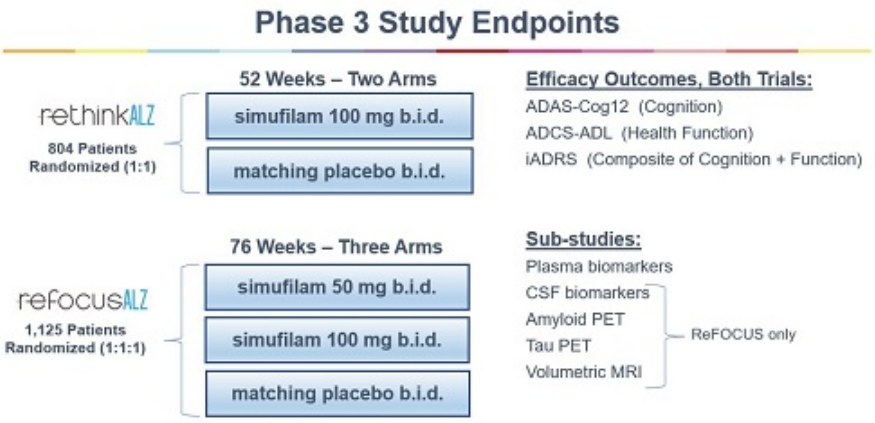
Phase 3 Clinical Program Overview

Our Phase 3 program consists of two large, double-blind, randomized, placebo-controlled studies of simufilam in patients with mild-to-moderate Alzheimer's disease dementia. Both studies are designed to measure changes in cognition and function during their treatment period. Some highlights of this clinical program are summarized in Figure 5.

Premier Research International is the CRO supporting the conduct of our Phase 3 clinical program. Our Phase 3 clinical sites are currently located in the United States, Canada, Puerto Rico, Australia, and South Korea.

Phase 3 data and samples for bioanalysis will be directly provided to and analyzed by independent, third-party commercial consulting firms.

Figure 5. Summary of Our Phase 3 Clinical Program



RETHINK-ALZ and REFOCUS-ALZ

In Fall 2021, we announced initiation of two Phase 3 studies of simufilam in mild-to-moderate Alzheimer's disease dementia. In November 2023, we had announced the completion of patient enrollment in both Phase 3 studies. A total of approximately 1,900 patients are randomized into these studies. Approximately 70% of randomized patients entered our Phase 3 studies with mild Alzheimer's disease (MMSE 20 to 27).

The first Phase 3 study, called RETHINK-ALZ, is designed to evaluate the safety and efficacy of oral simufilam 100 mg over 52 weeks (NCT04994483). Details of the RETHINK-ALZ Phase 3 study include:

- Approximately 800 patients are randomized into this study.
- Patients are randomized (1:1) to simufilam 100 mg tablets or matching placebo twice daily.
- Patients are treated for 52 weeks.

- Efficacy endpoints are ADAS-Cog12, a cognitive scale, and ADCS-ADL, a functional scale and iADRS, (which is a combination of scores from ADAS-Cog & ADCS-ADL). All three clinical measurements are standard psychometric assessment tools in trials of Alzheimer's disease.
- Other endpoints include plasma biomarkers of disease and NPI, a clinical tool that assesses the presence and severity of dementia-related behavior.
- No interim analyses on efficacy are planned.

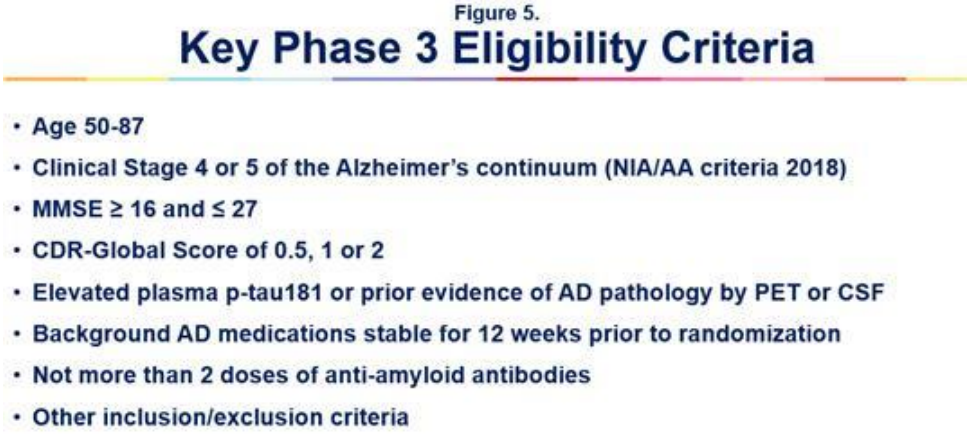
Our second Phase 3 study, called REFOCUS-ALZ, is designed to evaluate the safety and efficacy of oral simufilam 100 mg and 50 mg over 76 weeks (NCT05026177). Details of the REFOCUS-ALZ Phase 3 study include:

- Approximately 1,100 patients are randomized into this study.
- Patients are randomized (1:1:1) to simufilam 100 mg tablets, 50 mg tablets, or matching placebo twice daily.
- Patients are treated for 76 weeks.
- Efficacy endpoints are ADAS-Cog12, a cognitive scale, and ADCS-ADL, a functional scale and iADRS, (which is a combination of scores from ADAS-Cog & ADCS-ADL). All three clinical measurements are standard psychometric assessment tools in trials of Alzheimer's disease.
- Other endpoints include biomarkers of disease, MRI imaging and NPI, a clinical tool that assesses the presence and severity of dementia-related behavior.
- No interim analyses on efficacy are planned.

Phase 3 Entry Criteria

In our Phase 3 clinical studies, eligibility criteria are the requirements that patients must meet to be included in a study. These requirements help make sure that study participants are substantially and closely matched as a group in terms of specific factors such as age, disease or stage of disease, general health, and other key factors. Eligibility criteria can consist of inclusion criteria, which are required for a person to participate in the study, or exclusion criteria, which prevent a person from participating. See Figure 5A.

Figure 5.



Use of Plasma Phosphorylated-tau181 (p-tau181)

We believe plasma p-tau181 is a biomarker qualifier of Alzheimer's neuropathology. RETHINK-ALZ and REFOCUS-ALZ Phase 3 studies use a 'research use only', non-safety related exploratory p-tau181 plasma assay to qualify mild-to-moderate Alzheimer's patients. The plasma assay we use does not rely on age, APOE-gene status or complex algorithms to provide a result. P-Tau181 testing was performed by an independent commercial laboratory.

Data and Safety Monitoring Board (DSMB)

In March 2024, we announced that another routine, scheduled meeting of a DSMB recommended that both of our Phase 3 studies continue as planned, without modification. This was consistent with a DSMB meeting finding in September 2023. The DSMB only reviewed patient safety. It did not assess drug efficacy.

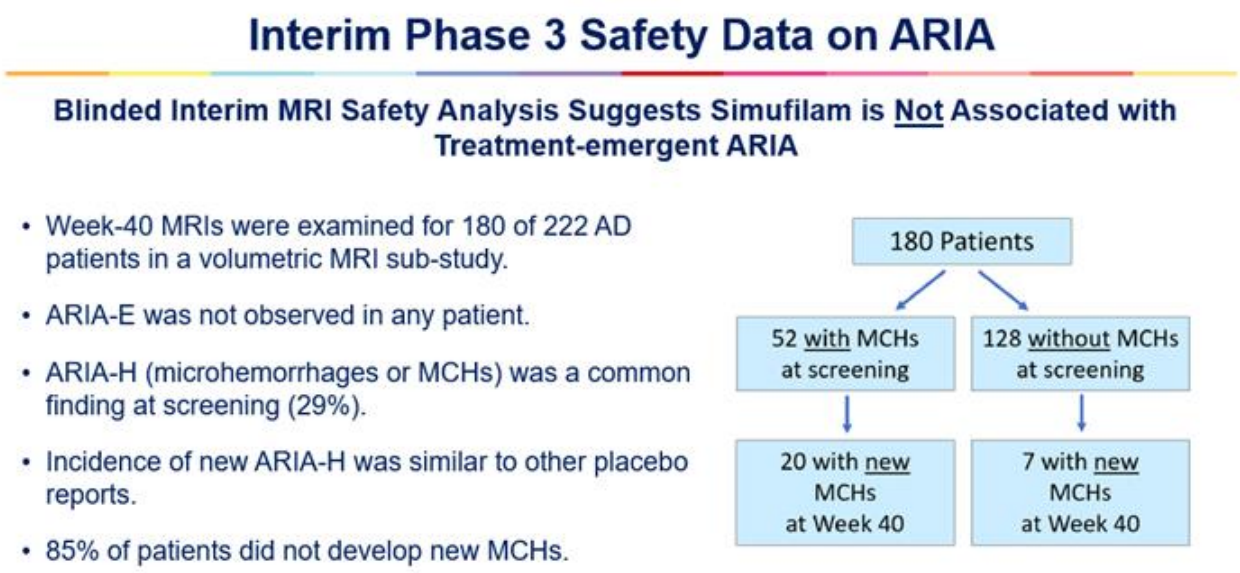
Interim MRI Safety Data

In October 2023, we announced a potentially significant safety finding based on interim magnetic resonance imaging (MRI) brain data from Alzheimer's patients who are enrolled in a Phase 3 clinical trial of simufilam. These MRI data suggest simufilam is not associated with treatment-emergent amyloid-related imaging abnormalities, or ARIA. MRIs were all analyzed for ARIA by independent, board-certified neuroradiologists.

ARIA is a medical term used to describe a spectrum of brain MRI imaging abnormalities, such as brain swelling and brain bleeds. ARIA is a known risk factor for Alzheimer's patients taking the class of drugs known as monoclonal antibodies directed against amyloid. In contrast to that class of drugs, simufilam is a small-molecule (oral) drug candidate.

The new safety finding is based on an independent, interim neuroradiological evaluation of brain MRIs taken at week 40 in a blinded sub-study of 180 Alzheimer's patients enrolled in REFOCUS-ALZ, our on-going 76-week Phase 3 clinical trial of simufilam in mild-to-moderate Alzheimer's. Final MRI data is expected at the conclusion of this Phase 3 study. See Figure 6.

Figure 6.



Status of Phase 3 Clinical Program

Our Phase 3 trials have randomized a total of approximately 1,900 patients with mild to moderate stages of Alzheimer's disease at baseline (MMSE 16-27), with approximately 800 patients randomized in the 52-week study (RETHINK-ALZ) and approximately 1,100 patients randomized in the 76-week study (REFOCUS-ALZ).

Approximately 70% of patients enrolled in our Phase 3 trials are diagnosed with mild Alzheimer's disease (MMSE 20-27), with remaining patients entering the study with moderate disease (MMSE 16-19). Since the distribution of patients randomized in these trials is numerically skewed towards mild patients, we expect to rely predominantly on outcomes from mild patients to evaluate drug safety and efficacy.

Over 555 patients have completed the 52-week RETHINK-ALZ study. Over 420 patients have completed the 76-week REFOCUS-ALZ study, for a total of over 975 completers.

All efficacy data from our Phase 3 program remain blinded. There are no interim analyses on efficacy outcomes.

We anticipate top-line data readout for our 52-week study (RETHINK-ALZ) by the end of 2024.

We anticipate top-line data readout for our 76-week study (REFOCUS-ALZ) approximately mid-year 2025.

In July 2024, we submitted to FDA for review a statistical analysis plan (SAP), which is a formal document defining the detailed analysis that our independent biostatisticians will undertake as to efficacy data collected in our Phase 3 trials. The SAP includes in-depth technical details and descriptions on the intended clinical trial analysis, the statistical methods and models that will be used, the population being analyzed, the data variables that will be analyzed, how missing data will be accounted for, descriptions of covariates to be included in the statistical model, and other statistical factors, all of which will be prospectively defined, documented and finalized prior to unblinding of any efficacy outcomes.

Phase 3 Drug Supply

We have a drug supply agreement with Evonik Industries AG for simufilam. Under the agreement, Evonik supplies and is expected to continue to 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. Other vendors supply excipients, the finished dosage form (i.e., simufilam tablets), drug packaging, package labeling and other critical components of the supply chain for Phase 3 drug supply.

Open-label Extension Study for the Phase 3 Program

In October 2022, we announced the initiation of an open-label extension study for our Phase 3 program. This study is designed to provide no-cost access to oral simufilam for up to one year to Alzheimer's patients who have successfully completed a Phase 3 study of simufilam and who meet other entry criteria and to generate additional long-term clinical safety data for oral simufilam 100 mg twice daily over 52 weeks. Each clinical investigational site and each patient chooses whether to participate in this open-label extension study with no obligation to participate.

Patient enrollment for this study began in November 2022, with approximately 89% of patients in Cassava's ongoing Phase 3 program have elected to continue with open-label treatment with simufilam after completion of the blinded trials.

Expansion of Open-Label Extension Studies

In July 2024, we announced our intention to extend the Phase 3 open-label extension trial as well as an ongoing open-label extension trial for patients in the Company's Phase 2 clinical programs, in each case by up to an additional 36 months. These amendments to the protocols will allow patients who have previously participated in an underlying trial of simufilam in Alzheimer's disease, if they desire, to continue open-label treatment with simufilam. This expansion of the open-label extension trials offers a bridge for any gap between patients ending treatment in a clinical trial and the Company reporting to regulatory authorities the results of the ongoing, randomized, placebo-controlled Phase 3 trials. The open-label extension can continue for up to 36 months or until a new drug application for simufilam has been reviewed by FDA. Cassava also announced that it plans to add cognition and plasma biomarker monitoring to its open-label extension trial for patients who have completed the Phase 3 trials in order to gather additional long-term data on the potential impact of simufilam treatment.

These expanded extension studies are designed to provide no-cost access to oral simufilam to Alzheimer's patients who have successfully completed a Phase 2 or Phase 3 study of simufilam and who meet other entry criteria. Each clinical investigational site must choose whether to participate in the open-label extension studies.

SavaDx

Our investigational product candidate, called SavaDx, is an early-stage program focused on detecting the presence of Alzheimer's disease from a small sample of blood. For business, technical and personnel reasons, we continue to prioritize the development of simufilam, our novel drug candidate, over SavaDx, our novel diagnostic candidate. SavaDx is a research-use only, non-safety related exploratory biomarker. Development activity related to SavaDx accounts for less than 1% of our research budget.

The regulatory pathway for SavaDx may eventually include formal analytical validation studies and clinical studies that support evidence of sensitivity, specificity and other variables in various healthy and diseased patient populations. We have not conducted such studies and do not expect to conduct such studies in 2024.

SavaDx is currently designed as an antibody-based detection system for altered filamin A (FLNA). Working with third parties, we are evaluating the use of mass spectrometry to detect FLNA, i.e., without the use of antibodies. These evaluations are on-going.

Expansion of Our Science to Other Indications

Protein misfolds occur in a wide variety of biological processes and diseases. We may leverage our scientific insights in neurodegeneration and neuroinflammation and advanced tools in molecular biology, biochemistry, and imaging to expand our science to other diseases. New indications and new drug development approaches may complement our initial focus on Alzheimer's disease.

Preclinical programs are always visionary, sometimes innovative and often of high biomedical potential. By definition, such programs are exploratory and risky. Most preclinical programs fail for scientific or other reasons, regardless of the amount of effort or resources that are brought to bear. For these reasons, we do not intend to disclose our preclinical programs until they become material to our pipeline of product candidates.

We Own Worldwide Rights to Our Neurodegeneration Program

We own intellectual property, including patents, patent applications, technology, trade secrets and know-how in the U.S. and other countries. The protection of patents, designs, trademarks and other proprietary rights that we own or license is critical to our success and competitive position. We consider the overall protection of our patents and other intellectual property rights to be of material value and act to protect these rights from infringement.

We seek to protect our technology by, among other methods, filing and prosecuting U.S. and foreign patents and patent applications with respect to our technology and products and their uses. The focus of our patent strategy is to secure and maintain intellectual property rights to technology for our program in neurodegeneration.

Simufilam was discovered and designed in-house and was characterized by our academic collaborators during research activities that were conducted from approximately 2008 to date. SavaDx is being developed in-house with outside collaborators. We own exclusive, worldwide rights to those drug and diagnostic 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 diseases currently runs through 2039 and includes nine issued U.S. patents. In addition, we have patent protection with respect to simufilam for use in treating certain cancers that runs through 2033. Our patent estate further includes patents and patent applications for related compounds and treatments. Corresponding foreign filings have been made for each of the U.S. filings.

Financial Overview

We have yet to generate any revenues from product sales. We have an accumulated deficit of $349.6 million at June 30, 2024. 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 clinical and preclinical 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 enrollment rates of clinical trials for our product candidates, timing of preclinical activities 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 in the future as we:

- continue our ongoing Phase 3 program with simufilam;
- manufacture large-scale supplies for simufilam;
- conduct other preclinical and clinical studies for our product candidates;
- 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;
- incur costs related to legal proceedings and claims, including U.S. government inquiries; and
- hire additional personnel.

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 expect to 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, certain collaborators, contract development and manufacturing organizations (CDMOs), CROs 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 development of simufilam. Research and development expenses for our investigational diagnostic product candidate, SavaDx, represented less than 1% of total research and development expenses for the periods presented. The following table summarizes expenses by category for research and development efforts (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Clinical trials	$ 10,877	$ 19,271	$ 22,169	$ 37,535
Pre-clinical projects	867	2,104	1,999	3,174
Chemical, Manufacturing and Controls costs (“CMC costs”)	398	1,518	1,193	2,232
Personnel related	1,615	1,398	3,260	2,823
Stock-based compensation	972	392	1,945	781
Other	469	286	865	544
	$ 15,198	$ 24,969	$ 31,431	$ 47,089

Clinical trial costs include the costs of our CRO. CMC costs include costs related to our contract development and manufacturing organizations. Research and development expenses include compensation, contractor fees and supplies as well as allocated common costs such as facilities.

Estimating the dates of completion of clinical development, and the costs to complete development, of our product candidates would be highly speculative and subjective. Pharmaceutical products take a significant amount of time to research, develop and commercialize. The clinical study portion of the development of a new drug alone usually spans several years. We expect our research and development expenses to decrease modestly in 2024 as a result of decreased spending for our Phase 3 program, as patient screening and enrollment are now complete for the Phase 3 clinical studies. The decrease in Phase 3 program costs is expected to be partially offset by increased enrollment in the open-label study as well as higher stock-based compensation expense. 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 Estimates

This discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as the reported expenses and net loss incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Valuation of Common Stock Warrant Liabilities

The fair value of common stock warrant liabilities was determined on the January 3, 2024 warrant distribution date using a Monte Carlo valuation model. Determining the appropriate fair value model and calculating the fair value of common stock warrants requires considerable judgment. Any change in the estimates used may cause the value to be higher or lower than that reported. Subsequent to their distribution, the common stock warrants were traded on the Nasdaq Capital Market under the trading symbol "SAVAW". The fair value of common stock warrant liabilities at March 31, 2024 was determined using the closing price for the common stock warrants on that date. May 2, 2024 was the final day of trading for the common stock warrants on the Nasdaq Capital Market. Subsequent to that date and through the Warrant Redemption beginning May 7, 2024, the warrants were considered to have no value since there was no active market for trading. All changes in the fair value are recorded in the statements of operations each reporting period. Fair value changes may be significantly different from those recorded in the financial statements due to of the use of judgment and the inherent uncertainty in estimating the fair value of these instruments in the initial valuation as of January 3, 2024, the warrant distribution date.

Legal and other contingencies

The Company is currently involved in various claims and legal and regulatory proceedings. The Company regularly reviews the status of each significant matter and assesses its potential financial exposure. If the potential loss from any claim or legal proceeding is considered probable and the amount can be reasonably estimated, the Company accrues a liability for the estimated loss. Significant judgment is required in both the determination of probability and whether an exposure is reasonably estimable. Our judgments are subjective based on the status of the legal or regulatory proceedings, the merits of our defenses and consultation with in-house and outside legal counsel. Because of uncertainties related to these matters, accruals are based only on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to its pending claims and legal and regulatory proceedings and may revise its estimates. Due to the inherent uncertainties of the legal and regulatory process, our judgments may be materially different than the actual outcomes.

Other than as described above, there have been no material changes to our critical accounting estimates during the six months ended June 30, 2024 from those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on February 28, 2024.

Results of Operations – Three and Six Months Ended June 30, 2024 and 2023

Research and Development Expense

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

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

Research and development expenses were $15.2 million and $25.0 million during the three months ended June 30, 2024 and 2023, respectively. This 39% decrease was due primarily to the completion of patient screening and enrollment for our Phase 3 clinical program in the fall of 2023. Patients are continually completing the Phase 3 program and a portion of completers are enrolling in the lower cost open-label extension study.

Research and development expenses were $31.4 million and $47.1 million during the six months ended June 30, 2024 and 2023, respectively. This 33% decrease was due primarily to the completion of patient screening and enrollment for our Phase 3 clinical program in the fall of 2023. Patients are continually completing the Phase 3 program and a portion of completers are enrolling in the lower cost open-label extension study.

We expect research and development expense to decrease modestly in future periods since patient screening and enrollment is complete for our Phase 3 clinical program. The decrease in Phase 3 program costs is expected to be partially offset by increased enrollment in the open-label study as well as higher stock-based compensation expense due to new grant awards in 2023.

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 for our Company owned office complex in Austin, Texas. Depreciation and amortization for office space leased but not occupied by the Company is included in general and administrative expense. Depreciation and amortization for office space occupied by the Company is allocated between general and administrative expense and research and development expense. We also incur expenses associated with operating as a public company, including additional legal fees, expenses related to compliance with the rules and regulations of the SEC and Nasdaq, additional insurance and audit expenses, investor relations activities, Sarbanes-Oxley compliance expenses and other administrative expenses and professional services.

General and administrative expenses were $46.2 million and $3.8 million during the three months ended June 30, 2024 and 2023, respectively. The significant increase was due primarily to a $40.0 million accrual for an estimated legal related loss contingency as well as a $1.2 million increase in stock-based compensation expense due to new grant awards in late 2023 and 2024, increased compensation costs and higher legal related expenses.

General and administrative expenses were $49.9 million and $8.2 million during the six months ended June 30, 2024 and 2023, respectively. The significant increase was due primarily to a $40.0 million estimated legal related loss contingency as well as $2.3 million increase in stock-based compensation expense due to new grant awards in late 2023 and 2024 and increased compensation costs. The increases were partially offset by a $1.2 million decrease in legal expenses as the Company met its insurance deductible in Q4 2023 and has recorded approximately $8.8 million in insurance recoveries during the six months ended June 30, 2024.

We expect general and administrative expense for 2024 will remain at high historic levels due to professional fees related to ongoing securities class action and derivative lawsuits and governmental investigations. In addition, stock-based compensation expense will be higher than historic levels due to 2023 and 2024 stock option grants and our anticipated hiring of a new Chief Executive Officer.

Interest Income

Interest income was $2.3 million and $2.2 million during the three months ended June 30, 2024 and 2023, respectively.

Interest income was $4.1 million and $4.2 million during the six months ended June 30, 2024 and 2023, respectively.

We expect interest income to decrease modestly over the remainder of 2024 as we utilize cash in our operations.

Change in fair value of warrants

The change in fair value of warrants was $65.1 million for the three months ended June 30, 2024. The change in fair value of warrants was $108.2 million for the six months ended June 30, 2024. There were no common stock warrants outstanding or change in fair value of warrants for the three and six months ended June 30, 2023. The 2024 change was attributable to a gain on the change in fair value of our liability-classified warrants from distribution on January 3, 2024 to their redemption in May 2024. The change in fair value was primarily driven by a decrease in fair value at redemption as there was little or no market trading activity and the warrants were redeemed for a nominal payment of $0.001 per warrant.

Other income, net

We record the activities related to leasing office space to third parties in buildings we own as other income, net, as leasing is not core to the Company's operations. Other income, net, was $99,000 and $203,000 during the three months ended June 30, 2024 and 2023, respectively. Other income, net, was $259,000 and $393,000 during the six months ended June 30, 2024 and 2023, respectively. Other income, net, was lower in the three and six months ended June 30, 2024 as due to higher vacancy rates in 2024 compared to the prior year periods. We expect other income, net, to decrease in 2024 as higher vacancy rates are expected to further lower rental income.

Depreciation and amortization for the office complex is included in general and administrative and research and development expense, and thus not reflected in other income, net.

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, 2024, cash and cash equivalents were $207.3 million.

2024 Common Stock Warrant Distribution

On January 3, 2024, we made a distribution of approximately 16.9 million warrants to purchase shares of our common stock to holders of record of our common stock as of the close of business on December 22, 2023.

Each warrant entitled the holder to purchase, at the holder's sole expense and exclusive election, at an exercise price of $33.00 per warrant, one and one-half shares of common stock (rounded down for any fractional shares).

On April 15, 2024, the Company announced that all outstanding warrants were to be redeemed on May 7, 2024 (the "Redemption Date"). The redemption price was equal to 1/10 of $0.01 per warrant. The warrants were exercisable at any time starting on January 3, 2024 until the business day prior to the Redemption Date.

From January 3, 2024 to March 31, 2024, a total of approximately 674,000 warrants were exercised resulting in net proceeds to the Company of approximately $22.3 million. The Company issued approximately 1.0 million shares of common stock from the exercise of warrants through March 31, 2024.

Subsequent to March 31, 2024 and through the Redemption Date, a total of approximately 3.15 million warrants were exercised resulting in gross proceeds to the Company of approximately $104.0 million. The Company issued approximately 4.7 million shares of common stock from the exercise of warrants from March 31, 2024 through the Redemption Date.

Gross proceeds in 2024 from the warrant distribution totaled approximately $126.3 million from the issuance of approximately 5.7 million common shares at $22.00 per share. Total net proceeds of the warrant distribution were approximately $123.6 million after deducting estimated exercise expenses.

After the first $20 million of gross proceeds, the Company was obligated to pay a commission of 2.5% of the gross proceeds from the sale of shares of common stock from warrant exercises to the Company's financial advisor for the warrant distribution. Total cost of warrant exercises through the Redemption Date were approximately $2.7 million.

At-the-Market Common Stock Offering

On May 1, 2023, we entered into 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 $200 million in common stock pursuant to a shelf registration statement that was filed with the SEC on May 1, 2023 and became effective immediately upon filing. We are obligated to pay a commission of up to 3% 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, 2024, and up to $200 million in common stock remains available under the ATM.

In March 2020, we entered into an at-the-market offering program ("2020 Program") to sell 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 gave notice of termination for the 2020 Program effective on April 26, 2023, which was effective May 1, 2023. There were no common stock sales under the 2020 Program through its termination.

2020 Cash Incentive Bonus Plan Obligations

In August 2020, the Company's Board of Directors (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.

As of December 31, 2022, the Company's independent directors were participants in the Plan. However, effective March 16, 2023, the Board amended the Plan to remove all independent directors as participants in the Plan and the independent directors consented to such removal. The independent directors' share of potential benefits under the Plan were completely forfeited to the Company and will not be allocated to any other participant under the Plan. Our independent directors have not received, and as a result of such amendment will never receive, any payments under the Plan.

The Company's market capitalization, including all outstanding stock options, was $89.4 million at the inception of the Plan in August 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 $111.4 million up to a hypothetical maximum of $289.7 million.

The Company's potential financial obligation to plan participants at June 30, 2024 totaled $6.5 million (after taking into account the March 2023 Plan amendment), 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 year ended December 31, 2021, the Company's market capitalization increased substantially. These increases triggered the achievement of 11 additional Plan milestones. Collectively, the achievement of such milestones could trigger potential Company obligations to Plan participants ranging from a minimum of $74.9 million up to a hypothetical maximum of $202.3 million, with exact amounts to be determined by the Compensation Committee and contingent upon future satisfaction of a Performance Condition.

No Valuation Milestones were achieved during the years ended December 31, 2023 and 2022 or the six months ended June 30, 2024.

No actual cash payments were authorized or made to participants under the Plan as of June 30, 2024, or through the filing date of this Quarterly Report on Form 10-Q.

Use of Cash

Net cash used in operating activities was $37.4 million for the six months ended June 30, 2024, resulting primarily from the net income of $31.2 million, stock-based compensation expense of $4.9 million and an increase in accounts payable and accrued expenses of $42.0 million, offset by a change in fair value of warrants of $108.2 million, an decrease in accrued developmental expenses of $1.4 million and a decrease in in prepaid and other current assets of $6.3 million.

Net cash used in operating activities was $33.2 million for the six months ended June 30, 2023, resulting primarily from the net loss of $50.6 million, partially offset by an increase in accounts payable and accrued expenses of $6.7 million, an increase in accrued developmental expenses of $4.8 million, a decrease in in prepaid and other current assets of $4.1 million and stock-based compensation expense of $1.5 million.

Net cash used in investing activities during the six months ended June 30, 2024 was $29,000 for computers and equipment and other assets.

Net cash used in investing activities during the six months ended June 30, 2023 was $0.4 million as final payment was made on renovations and fixtures for our corporate headquarters.

Net cash provided by financing activities during the six months ended June 30, 2024 was $123.6 million of net proceeds from the exercise of warrants.

Net cash provided by financing activities during the six months ended June 30, 2023 was $1.0 million, from the exercise of stock options.

Property and Leases

We own an office complex in Austin, Texas, a portion of which serves as our corporate headquarters. This property is intended to accommodate our potential growth and expansion of our operations in the coming years. Maintenance, physical facilities, leasing, property management and other key responsibilities related to property ownership are outsourced to professional real-estate managers. The office complex measures approximately 90,000 rentable square feet. At June 30, 2024, we occupied approximately 25% of the property with the remainder either leased or available for lease to third parties. Most tenant leases will expire in 2024. We believe tenant leases that expire in 2024 may likely not be extended, renewed or re-leased beyond their expiry date, in which case we will no longer receive rental payments or reimbursement for shared expense for such office space.

Other Commitments

We have an accumulated deficit of $349.6 million as of June 30, 2024. 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 cash and cash equivalents 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***

We are exposed to market risks in the ordinary course of our business, primarily related to interest rate sensitivities and, to a lesser extent, currency fluctuations related to our clinical operations outside the U.S.

Interest Rate Sensitivity

We are exposed to market risk related to changes in interest rates. We had cash and cash equivalents of $207.3 million as of June 30, 2024, which consisted primarily of U.S. Treasury securities and money market accounts.

The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain investment vehicles with high credit quality and short-term duration, in accordance with our Board-approved investment policy. Such interest-earning instruments carry a degree of interest rate risk. However, due to the generally short-term maturities and low risk profile of our cash equivalents, an immediate 100 basis point increase or decrease in interest rates during any of the periods presented would increase or decrease our annual net loss by less than $2.1 million in our condensed consolidated financial statements.

Item 4. ***Controls and Procedures***

Evaluation of disclosure controls and procedures. Our management, with the participation of our Executive Chairman of the Board of Directors 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 Executive Chairman of the Board of Directors (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, 2024, our Executive Chairman of the Board of Directors 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, 2024 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***

We are, and from time to time, we may become involved in litigation or other legal proceedings and claims, including U.S. government inquiries, investigations and Citizen Petitions submitted to FDA. In addition, we have received and from time to time may receive inquiries from government authorities relating to matters arising from the ordinary course of business. The outcome of these proceedings is inherently uncertain. Regardless of outcome, legal proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors. At this time, no assessment can be made as to their likely outcome or whether the outcome will be material to us. We believe that our total provisions for legal matters are adequate based upon currently available information. Additional information regarding our legal proceedings is included in this Quarterly Report on Form 10-Q in Note 11 to our condensed consolidated financial statements entitled, "Contingencies."

Item 1A. ***Risk Factors***

Please refer to "*Risk Factors*" *in Part I, Item 1A of our 2023 Annual Report on Form 10-K for additional information on our current risks. Other than the supplemental risk factors provided below, there have been no material changes in our risk factors from those disclosed in our Annual Report on Form 10-K. The risks and uncertainties described in our 2023 Annual Report on Form 10-K and provided below 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.*

The validity of CSF biomarker assays and bioanalysis conducted by CUNY for the Company's Phase 2b Study has been called into question.

The Company's Phase 2b Study was designed as a 28-day, approximately 60-patient, randomized, double-blind, placebo-controlled, multiple dose study. A primary objective of the Phase 2b Study was to measure changes in levels of cerebral spinal fluid ("CSF") biomarkers in study participants from baseline value to Day 28. CSF biomarker assays and related bioanalysis for the Phase 2b Study (the "CUNY Bioanalysis") were conducted by the laboratory at CUNY of Dr. Hoau-Yan Wang, formerly a paid scientific collaborator, consultant and advisor to Cassava. Based on the CUNY Bioanalysis, Cassava reported statistically significant improvements in CSF biomarkers in treatment groups as compared to the placebo group for the Phase 2b Study.

On June 28, 2024, the DOJ announced that a federal grand jury in the U.S. District Court for the District of Maryland returned an indictment of Dr. Wang alleging that he caused Cassava to submit grant applications to NIH that contained false and fraudulent representations about his research. Among other things, the indictment alleges that Dr. Wang made materially false, fraudulent, and misleading statements to NIH regarding the mechanism by which simufilam was designed to treat Alzheimer's disease and the improvement of certain Alzheimer's disease indicators in patients treated with simufilam, and that Dr. Wang manipulated or otherwise fabricated research results, including Western Blot images that he prepared.

As part of the Internal Investigation being conducted by the Ad Hoc Investigation Committee of the Company's Board of Directors, the Committee is evaluating information contained in the DOJ indictment of Dr. Wang as well as information from the Company's ongoing discussions with the SEC. To date, the Internal Investigation has determined that certain statistical information contained in an attachment to an email sent by a former senior employee of Cassava to Dr. Wang before the CUNY Bioanalysis of CSF biomarkers was conducted could have been used to unblind him as to some number of Phase 2b Study participants. Unblinded information, if accessed in connection with bioanalysis, could be improperly utilized to manipulate underlying samples or data to skew reported results.

The Internal Investigation has not, to date, determined, and may never be able to determine with any reasonable degree of certainty, whether Dr. Wang unblinded himself as to some number of Phase 2b Study participants. Nevertheless, the fact that Dr. Wang possessed information that could have been used to so unblind himself, together with the allegations in the DOJ indictment, undermine the blinded study design and create substantial uncertainty about the validity of the CUNY Bioanalysis of CSF biomarkers. There can be no assurance that such uncertainty will not adversely impact the FDA's review of an NDA with respect to simufilam following completion of our Phase 3 clinical studies or cause the FDA to request additional information regarding simufilam.

Accordingly, in light of the foregoing uncertainties, you should not place undue reliance on the CUNY Bioanalysis of CSF biomarkers reported by the Company in connection with the Phase 2b Study.

We are subject to lawsuits and governmental investigations and inquiries.

We are defending ourselves in a number of lawsuits, including securities class action and shareholder derivative actions, and the Company, as well as two former senior employees of the Company, have been and may continue to be subject to governmental investigations and inquiries. Defending litigation and responding to governmental investigations is expensive and time consuming and may divert the time and attention of our management away from the conduct of our primary business. Moreover, the allegations underlying such litigation and governmental investigations have damaged our business reputation, which may make it difficult to, among other things: raise capital or engage in a strategic transaction on acceptable terms or at all; hire and retain third-party consultants and collaborators; recruit and retain patients for our studies; and attract and retain qualified executive officers, other employees and directors. The foregoing matters may exacerbate other risks discussed in our Annual Report on Form 10-K under the Caption "Item 1A. Risk Factors" and have a negative impact on the perception of our company by investors, patients, investigators, collaborators, and others.

As a result of current or future lawsuits, we may have to pay significant damages or amounts in settlement above insurance coverage, including amounts in respect of indemnification obligations of the Company to former officers and senior employees. An unfavorable outcome or prolonged litigation could materially and adversely impact our business, operating results, and financial condition, including our cash runway. In addition, current or future government investigations and inquiries could subject us to various sanctions, including significant penalties, our being prevented from receiving government grants, and other punitive measures.

While we cannot estimate our potential exposure to future litigation, regulatory claims, investigations or proceedings at this time, we have already incurred significant expense related to litigation, government investigations and the Internal Investigation and expect to continue to incur significant expense.

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***

During the quarter ended June 30, 2024, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) informed us of the adoption or termination of a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408.

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.	
3.1	Amended and Restated Certificate of Incorporation.	10-Q	7/29/2005	3.1	
3.2	Certificate of Amendment of Restated Certificate of Incorporation.	8-K	5/8/2017	3.1	
3.3	Certificate of Amendment of Restated Certificate of Incorporation.	10-K	3/29/2019	3.3	
3.4	Amended and Restated Bylaws of Cassava Sciences, Inc.	8-K	9/13/2023	3.4	
4.1	Warrant Agreement (including Form of Warrant), dated January 3, 2024, between Cassava Sciences, Inc., Computershare Inc., and Computershare Trust Company, N.A.	8-K	1/3/2024	4.1	
10.1	Employment agreement amendment, dated May 20, 2024, by and between Cassava Sciences, Inc. and Eric J. Schoen	8-K	5/22/2024	10.1	
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1+	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.				X
101.INS	Inline XBRL Instance Document - (the instant document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X
104.	Cover Page Interactive Data File –(formatted as Inline XBRL and contained in Exhibit 101).				X

+The certification furnished in Exhibit 32.1 hereto is deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Exchange Act of 1934. Such certification will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

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/ RICHARD J. BARRY
Richard J. Barry,
Executive Chairman of the Board of Directors,
(Principal Executive Officer)

Date: August 8, 2024

/s/ ERIC J. SCHOEN
Eric J. Schoen,
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: August 8, 2024

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

I, Richard J. Barry, 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/ RICHARD J. BARRY
Richard J. Barry,
Executive Chairman of the Board of Directors,
(Principal Executive Officer)

Date: August 8, 2024

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

Date: August 8, 2024

CERTIFICATION OF THE EXECUTIVE CHAIRMAN OF THE BOARD OF DIRECTORS 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, 2024, 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 8, 2024

/s/ RICHARD J. BARRY
Richard J. Barry
Executive Chairman of the Board of Directors,
(Principal Executive Officer)

/s/ ERIC J. SCHOEN
Eric J. Schoen,
Chief Financial Officer
(Principal Financial and Accounting Officer)