CASSAVA SCIENCES INC

FORM 10-Q
(Quarterly Report)

Filed 08/14/25 for the Period Ending 06/30/25

Address	6801 N CAPITAL OF TEXAS HIGHWAY BUILDING 1; SUITE 300 AUSTIN, TX, 78731
Telephone	512-501-2444
CIK	0001069530
Symbol	SAVA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

Table of Contents

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, 2025
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	48,307,896 Shares Outstanding as of August 12, 2025

CASSAVA SCIENCES, INC.
TABLE OF CONTENTS

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, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 112,381	$ 128,574
Prepaid expenses and other current assets	2,440	7,958
Total current assets	114,821	136,532
Property and equipment, net	20,563	21,001
Total assets	$ 135,384	$ 157,533
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 42,822	$ 7,654
Accrued development expense	3,788	2,440
Accrued compensation and benefits	563	1,357
Other current liabilities	159	299
Total current liabilities	47,332	11,750
Other non-current liabilities	79	79
Total liabilities	47,411	11,829
Commitments and contingencies (Notes 8, 9 and 10)		
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; 48,307,896 and 48,203,179 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	48	48
Additional paid-in capital	560,663	550,767
Accumulated deficit	(472,738)	(405,111)
Total stockholders' equity	87,973	145,704
Total liabilities and stockholders' equity	$ 135,384	$ 157,533

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,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 5,116	$ 15,198	$ 18,782	$ 31,431
General and administrative	40,276	46,204	51,196	49,905
Total operating expenses	45,392	61,402	69,978	81,336
Operating loss	(45,392)	(61,402)	(69,978)	(81,336)
Interest income	1,214	2,316	2,479	4,092
Other income (loss), net	(46)	99	(128)	259
Gain from change in fair value of warrant liabilities	—	65,142	—	108,183
Net income (loss)	$ (44,224)	$ 6,155	$ (67,627)	$ 31,198
Shares used in computing net income (loss) per share, basic	48,308	46,202	48,285	44,601
Net income (loss) per share, basic	$ (0.92)	$ 0.13	$ (1.40)	$ 0.70
Numerator, diluted:				
Net income (loss)	$ (44,224)	$ 6,155	$ (67,627)	$ 31,198
Adjustment for change in fair value of warrant liabilities	—	—	—	(43,793)
Adjusted numerator, diluted	$ (44,224)	$ 6,155	$ (67,627)	$ (12,595)
Shares used in computing net income (loss) per share, diluted	48,308	46,202	48,285	45,152
Net income (loss) per share, diluted	$ (0.92)	$ 0.13	$ (1.40)	$ (0.28)

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, 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 stock options	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
Balance at December 31, 2024	48,203,179	$ 48	$ 550,767	$ (405,111)	$ 145,704
Stock-based compensation for:					
Stock options for employees	—	—	5,189	—	5,189
Stock options for non-employees	—	—	36	—	36
Issuance of common stock pursuant to exercise of stock options	104,717	—	90	—	90
Net loss	—	—	—	(23,403)	(23,403)
Balance at March 31, 2025	48,307,896	$ 48	$ 556,082	$ (428,514)	$ 127,616
Stock-based compensation for:					
Stock options for employees	—	—	4,545	—	4,545
Stock options for non-employees	—	—	36	—	36
Net loss	—	—	—	(44,224)	(44,224)
Balance at June 30, 2025	48,307,896	$ 48	$ 560,663	$ (472,738)	$ 87,973

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, 2025	2024
Cash flows from operating activities:		
Net income (loss)	$ (67,627)	$ 31,198
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	9,806	4,939
Gain from change in fair value of warrant liabilities	—	(108,183)
Depreciation and amortization	438	613
Changes in operating assets and liabilities:		
Prepaid and other current assets	5,518	(6,334)
Accounts payable and accrued expenses	35,168	41,979
Accrued development expense	1,348	(1,441)
Accrued compensation and benefits	(794)	18
Other liabilities	(140)	(157)
Net cash used in operating activities	(16,283)	(37,368)
Cash flows from investing activities:		
Purchases of property and equipment	—	(29)
Net cash used in investing activities	—	(29)
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	90	—
Net cash provided by financing activities	90	123,552
Net increase (decrease) in cash and cash equivalents	(16,193)	86,155
Cash and cash equivalents at beginning of period	128,574	121,136
Cash and cash equivalents at end of period	$ 112,381	$ 207,291
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, 2025 are not necessarily indicative of the results that may be expected for any other interim period or for the year 2025. 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, 2024.

Liquidity

The Company has incurred significant net losses and negative cash flows since inception, and as a result has an accumulated deficit of $472.7 million at June 30, 2025. 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 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, 2025 and December 31, 2024.

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.

The Company's reportable segment reflects the manner in which its chief operating decision maker ("CODM") allocates resources and assesses performance. The Company's CODM is the President and Chief Executive Officer. The primary measure used by the Company's CODM for purposes of allocating resources is based on net loss that also is reported on the consolidated statements of operations as consolidated net loss. The measure of segment assets is reported on the condensed consolidated balance sheets as cash and cash equivalents.

The Company has not generated any product revenue in the current period and expects to continue to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through stages of development and clinical trials.

As such, the CODM uses cash forecast models in deciding how to invest in the development of novel drugs and diagnostics. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss is used to monitor budget versus actual results. Monitoring budgeted versus actual results, net cash used in operating activities for the period and cash on hand are used in assessing performance of the segment.

The following table summarizes expenses by category regularly reviewed by the CODM (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Operating expenses				
Research and development	$ (5,116)	$ (15,198)	$ (18,782)	$ (31,431)
General and administrative	(40,276)	(46,204)	(51,196)	(49,905)
Other segment items(a)	1,168	67,557	2,351	112,534
Net income (loss)	$ (44,224)	$ 6,155	$ (67,627)	$ 31,198

(a) Other segment items include interest income, other income, net and gain from change in fair value of warrant liabilities.

The following table summarizes assets regularly reviewed by the CODM (in thousands):

	June 30, 2025	December 31, 2024
Cash and cash equivalents	$ 112,381	$ 128,574

For the six months ended June 30, 2025 and 2024, the net cash used in operating activities was $16.3 million and $37.4 million, respectively.

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 one to 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 anti-dilutive. A net loss causes all potentially dilutive securities to be anti-dilutive. 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,	
	2025	2024	2025	2024
Numerator, basic:				
Net income (loss)	$ (44,224)	$ 6,155	$ (67,627)	$ 31,198
Denominator, basic:				
Weighted average common shares outstanding	48,308	46,202	48,285	44,601
Net income (loss) per share, basic	$ (0.92)	$ 0.13	$ (1.40)	$ 0.70
Numerator, diluted:				
Net income (loss)	$ (44,224)	$ 6,155	$ (67,627)	$ 31,198
Adjustment for change in fair value of warrant liabilities	—	—	—	(43,793)
Adjusted numerator, diluted	$ (44,224)	$ 6,155	$ (67,627)	$ (12,595)
Denominator, diluted:				
Weighted average common shares outstanding	48,308	46,202	48,285	44,601
Dilutive effect of common stock warrants	—	—	—	551
Weighted average dilutive common shares	48,308	46,202	48,285	45,152
Net income (loss) per share, diluted	$ (0.92)	$ 0.13	$ (1.40)	$ (0.28)
Dilutive common stock options excluded from net income (loss) per share, diluted	4,176	2,703	3,910	2,674
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 and six months ended June 30, 2025 and 2024 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 period 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 condensed consolidated 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.

There were no warrants outstanding at June 30, 2025 or December 31, 2024.

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 CIB 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 9 for further discussion of the CIB Plan.

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.

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 were no insurance recoveries during the three and six months ended June 30, 2025. There was approximately $5.8 million and $8.8 million of insurance recoveries recorded during the three and six months ended June 30, 2024, respectively.

Related Party Transactions

On July 15, 2024, our former President and Chief Executive Officer resigned from the Company, effective as of September 13, 2024 (the "Effective Date"). Pursuant to the terms of his employment agreement, our former President and Chief Executive Officer is receiving severance compensation equal to $1.23 million paid ratably over twelve months following the Effective Date. The full amount of severance compensation was included in general and administrative expense in the period the resignation was tendered and no severance compensation relating to this agreement was recognized in the three and six months ended June 30, 2025 or 2024.

On July 16, 2024, our former Senior Vice President (SVP), Neuroscience agreed to step down from her employment with the Company, effective immediately. Our former SVP, Neuroscience is the spouse of our former President and Chief Executive Officer. Pursuant to a separation agreement, our former SVP, Neuroscience is receiving severance compensation equal to $0.5 million paid in quarterly installments over twelve months. The full amount of severance compensation was included in research and development expense in the period the agreement providing for severance was executed and no severance compensation relating to this agreement was recognized in the three and six months ended June 30, 2025 or 2024.

Included in accrued compensation and benefits at June 30, 2025 and December 31, 2024 is approximately $0.3 and $1.2 million, respectively, of accrued severance costs for the two former senior officers.

On July 16, 2024, the Company entered into a one-year consulting agreement with the Company's former SVP, Neuroscience. Pursuant to the terms of the consulting agreement, the consultant is providing services for purposes of providing information and support for scientific research and/or obtaining governmental approval for the Company's products. The Company agreed to pay $500 per hour for such consulting services. The Company incurred fees totaling $20,000 under the consulting agreement during the three and six months ended June 30, 2025. The Company did not incur any fees under the consulting agreement during the three and six months ended June 30, 2024.

On June 20, 2025, the Company entered into a one-year consulting agreement with James W. Kupiec, M.D., the Company's former Chief Medical Officer. Pursuant to the terms of the consulting agreement, the consultant is providing services relating to Company manuscripts and publications. The Company agreed to pay a fixed fee totaling $42,000 for such consulting services. The Company incurred fees totaling $21,000 under the consulting agreement during the three and six months ended June 30, 2025.

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 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. This ASU includes amendments that require entities to bifurcate specified expense line items on the income statement into underlying components, including employee compensation, depreciation, and intangible asset amortization, as applicable. Qualitative descriptions of the remaining components are required. These enhanced disclosures are required for both interim and annual periods. In January 2025, the FASB subsequently issued ASU 2025-01, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date, to provide clarification on the ASU's effective date. The new standard is effective for fiscal years beginning after December 15, 2026 on a prospective basis with the option to apply it retrospectively, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The adoption of this guidance will result in the Company being required to include enhanced disclosures around income statement expenses.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The ASU requires that an entity disclose specific categories in the effective tax rate reconciliation as well as reconciling items that meet a quantitative threshold. Further, the ASU requires additional disclosures on income tax expense and taxes paid, net of refunds received, by jurisdiction. The new standard is effective for annual periods beginning after December 15, 2024 on a prospective basis with the option to apply it retrospectively. Early adoption is permitted. The adoption of this guidance will result in the Company being required to include enhanced income tax related disclosures.

Note 3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets at June 30, 2025 and December 31, 2024 consisted of the following (in thousands):

	June 30, 2025	December 31, 2024
Prepaid insurance	$ 5	$ 800
Contract research organization and other deposits	1,466	6,173
Interest receivable	835	947
Other	134	38
Total prepaid expenses and other current assets	$ 2,440	$ 7,958

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. 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, 2025, the Company occupied approximately 25% of the property with the remainder either leased or available for lease to third parties. Gross rental income under existing third-party leases at June 30, 2025 is expected to total $0.2 million in 2025, $0.4 million in 2026 and $0.2 million in 2027.

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,	
	2025	2024	2025	2024
Lease revenue	$ 110	$ 314	$ 246	$ 717
Property operating expenses	(156)	(215)	(374)	(458)
Other income, net	$ (46)	$ 99	$ (128)	$ 259

The Company had accrued property taxes related to the building totaling $0.1 million and $0.3 million at June 30, 2025 and December 31, 2024, respectively, included in other current liabilities.

Note 5. Property and equipment

The components of property and equipment, net, as of June 30, 2025 and December 31, 2024 were as follows (in thousands):

	June 30, 2025	December 31, 2024
Land	$ 3,734	$ 3,734
Buildings	15,980	15,980
Site improvements	494	494
Tenant improvements	3,062	3,062
Furniture and equipment	875	875
Construction in progress	55	55
Other	27	37
Gross property and equipment	$ 24,227	$ 24,237
Accumulated depreciation	(3,664)	(3,236)
Property and equipment, net	$ 20,563	$ 21,001

Depreciation expense for property and equipment was $0.2 million and $0.3 million for the three months ended June 30, 2025 and 2024, respectively. Depreciation expense for property and equipment was $0.4 million and $0.6 million for the six months ended June 30, 2025 and 2024, respectively.

Note 6. Stockholders' Equity and Stock-Based Compensation Expense

Common Stock Warrant Distribution

See Notes 2 and 11 regarding the distribution of common stock warrants on January 3, 2024.

Stock Option and Performance Award Activity in 2025

During the six months ended June 30, 2025, 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, 2024	4,463,028	7,142
Options granted	1,467,000	—
Options exercised	(225,209)	—
Options forfeited/canceled	(1,359,449)	—
Outstanding as of June 30, 2025	4,345,370	7,142

The weighted average exercise price per share of options outstanding at June 30, 2025 was $15.59. As outstanding options vest over the current remaining vesting period of 2.5 years, the Company expects to recognize stock-based compensation expense of $30.6 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 months ended June 30, 2025, there were no stock options exercised. During the six months ended June 30, 2025, there were 225,209 stock options exercised. Of the stock options exercised, 120,492 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 $90,000 during the six months ended June 30, 2025.

Stock-based Compensation Expense in 2025

During the three and six months ended June 30, 2025 and 2024, the Company's stock-based compensation expense was as follows (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Research and development	$ 1,162	$ 972	$ 3,534	$ 1,945
General and administrative	3,420	1,632	6,272	2,994
Total stock-based compensation expense	$ 4,582	$ 2,604	$ 9,806	$ 4,939

The Company estimates forfeitures for each award in determining stock-based compensation expense. The Company recorded $0.6 million and $0.2 million of estimated forfeitures during the three and six months ended June 30, 2025, respectively. There were no estimated forfeitures during the three and six months ended June 30, 2024.

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 in May 2022 (the "2018 Plan") and determines the terms and conditions of each option granted, consistent with the terms of the 2018 Plan. The Company's employees, directors, and consultants are eligible to receive awards under the 2018 Plan, including grants of stock options and Performance Awards. Share-based awards generally expire 10 years from the date of grant. The 2018 Plan provides for issuance of up to 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 7. Income Taxes

The Company did not provide for income taxes during the three and six months ended June 30, 2025 because it has projected a taxable net loss for the full year 2025 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, 2024.

Note 8. Commitments

The Company conducts its product research and development programs through a combination of internal and collaborative programs that include, among others, arrangements with universities, contract research organizations and clinical research sites. The Company has contractual arrangements with these organizations that are cancelable. The Company's obligations under these contracts are largely based on services performed. The Company also had non-cancellable commitments for the manufacture of simufilam's active pharmaceutical ingredient totaling approximately $1.2 million recorded in prepaid expenses and other current assets at June 30, 2025. The Company is dependent on contract development and manufacturing organizations for the manufacture of all our materials for clinical studies.

On February 26, 2025, the Company entered into a License Agreement (the "License Agreement") with Yale University ("Yale") pursuant to which the Company was granted exclusive worldwide rights, with rights to sublicense, to Yale's interest in certain patent and other intellectual property rights that could be useful or necessary to the development and commercialization of simufilam for the treatment of Tuberous Sclerosis Complex ("TSC")-related epilepsy and other potential indications. Pursuant to the License Agreement, the Company has agreed to use reasonable commercial efforts to implement a plan that it has designed for such development and commercialization. In exchange for the rights acquired pursuant to the License Agreement, the Company agreed to pay Yale (i) a nominal upfront license fee, (ii) payments upon the achievement of specified clinical, regulatory and commercial milestones, totaling up to $4.5 million and (iii) upon transfer to a third party in connection with a regulatory priority review voucher, if issued, a low-to-mid double digit percentage of any consideration received for such transfer. The Company also agreed to pay Yale tiered royalties, ranging from a low- to mid- single digit percentage, on aggregate net sales of licensed products, subject to tiered minimum annual royalty payments ranging from the low- to mid- hundreds of thousands of dollars.

Unless earlier terminated, the License Agreement will continue on a country-by-country basis until the later of (i) the date on which the last valid claim of the license patents expires or otherwise lapses, (ii) the end of any government or regulatory exclusivity period, and (iii) 10 years following the date of first sale of licensed product in such country.

Note 9. 2020 Cash Incentive Bonus Plan

In August 2020, the Board approved the CIB Plan. The CIB Plan was subsequently amended, as described below on March 6, 2025. The CIB Plan was established as an "at-risk" cash bonus program that would reward CIB Plan participants with additional cash compensation in lockstep with significant increases in the Company's market valuation (as measured by market capitalization or potential merger consideration). The CIB Plan is considered "at-risk" because CIB Plan participants will not receive a cash bonus unless the Company's market valuation 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. CIB Plan participants will be paid all earned cash bonuses allocated under the CIB Plan in the event of a Merger Transaction.

Because of the inherent discretion and uncertainty regarding the CIB Plan requirements, the Company has concluded that a CIB Plan grant date has not occurred as of June 30, 2025.

The Company's market valuation 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. This constitutes a market condition under applicable accounting guidance.

The CIB Plan (as amended March 6, 2025) triggers a potential cash bonus each time the Company's market valuation increases significantly, up to a maximum $5 billion in market capitalization (or up to a maximum $8 billion in merger consideration). The CIB Plan specifies incremental amounts between $200 million and $5 billion in market capitalization (or $8 billion in merger consideration) (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 based on market capitalization 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 (the "Market Capitalization Conditions").

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, CIB Plan participants may never 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 Valuation Milestones, when a Performance Condition is considered probable of being met.

In October 2020, the Company achieved the first Valuation Milestone based on market capitalization. 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 a March 2023 CIB Plan amendment), subject to future satisfaction of a Performance Condition. There is no continuing service requirement for CIB Plan participants once the Compensation Committee approves a cash bonus award.

During the year ended December 31, 2021, the Company achieved 11 additional Valuation Milestones based on market capitalization. The achievement of these 11 milestones in 2021 triggered a non-discretionary potential Company obligation to the Company's Chairman, President and CEO (assuming such person holds all three such offices) of $74.3 million (after taking into account a March 2023 CIB Plan amendment) and contingent upon future satisfaction of a Performance Condition. However, no compensation expense has been recorded and no payments have been made since no grant date has occurred and no Performance Conditions are considered probable of being met.

No Valuation Milestones were achieved during the six months ended June 30, 2025 and the years ended December 31, 2024, 2023 and 2022.

On February 13, 2025, the Compensation Committee concluded that no discretionary cash bonus amounts would be awarded for the 11 Valuation Milestones achieved in 2021 nor for any remaining CIB Plan Valuation Milestones which have not been achieved. Thus, the only CIB Plan participant who could be eligible for cash bonus amounts based on future Valuation Milestone achievement is the Chairman, President and CEO (assuming such person holds all three such offices), providing that, other than in connection with a Merger Transaction, no bonus payments will be made to such person unless and until the U.S. Food and Drug Administration has approved simufilam for any indication.

As discussed in Note 10, on January 24, 2025, the Delaware Court of Chancery entered a Final Order and Judgment approving the Stipulation and dismissing an action related to the CIB Plan with prejudice. The Final Order and Judgment required the Company to further amend the CIB Plan, as provided in the Stipulation, which was completed on March 6, 2025. The March 6, 2025 Amendment specifies that upon the occurrence of a Merger Transaction, the Chairman, President and CEO (assuming such person holds all three such offices) will not be entitled to any payments in respect of any Market Capitalization Conditions, but will instead be entitled to receive a bonus payment based upon the Merger Transaction only. Cash bonuses to the Chairman, President and CEO (assuming such person holds all three offices) are not subject to discretionary allocation under the CIB Plan. No person currently holds all three offices of Chairman, President and CEO.

No actual cash payments were authorized or made to participants under the CIB Plan through June 30, 2025 and the date of filing of this Quarterly Report on Form 10-Q.

Note 10. 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 the U.S. Food and Drug Administration ("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.

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 ("DOJ") and document requests from the SEC, 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, the CID and requests for information.

On September 26, 2024, the Company announced that it had reached a settlement with the SEC resolving the SEC investigation of the Company's disclosures regarding its Phase 2b clinical trial of simufilam for the treatment of Alzheimer's disease (the "Phase 2b Study") and related matters. The SEC also agreed to a settlement with two former senior employees of the Company. Pursuant to these settlements, the U.S. District Court for the Western District of Texas (the "Texas District Court") entered final consent judgment on October 18, 2024, on a complaint filed by the SEC against the Company and its two former senior employees. The Company has neither admitted nor denied the allegations of the complaint. The SEC's complaint alleged that certain disclosures by the Company regarding the Phase 2b Study violated certain federal securities laws and SEC rules, including negligence-based disclosure violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act of 1933, as amended (the "Securities Act"), as well as recordkeeping and reporting requirements under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The complaint alleges that the Company's SEC reports and other public statements regarding the Phase 2b Study negligently contained materially misleading statements and omissions. The SEC's allegations with respect to the Company's two former employees relate to these employees' roles in such disclosures. Under its settlement, the Company consented to a permanent injunction against future violations of Section 17(a) of the Securities Act, Section 13(a)(1) of the Exchange Act and Rules 12b-20, 13a-1, 13a-11 and 13a-13 under the Exchange Act. In addition, the Company paid a civil monetary penalty of $40 million in November 2024.

The Company continues to cooperate with the DOJ related to requests for documents and information, including those related to conduct alleged in the indictment of Dr. Hoau-Yan Wang announced by DOJ on June 28, 2024. The Company cannot predict the outcome or impact of ongoing matters, including whether a government authority may pursue an enforcement action against the Company or others. The Company does not at this time anticipate, however, that DOJ will bring criminal charges against or seek a criminal resolution with the Company.

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 Texas District Court. The complaints seek unspecified compensatory damages and other relief on behalf of a purported class of purchasers of the Company's securities.

On June 30, 2022, a federal judge consolidated the four class action lawsuits into one case (the "Consolidated Securities Action") 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 Texas District 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 Texas District Court granted that Motion on June 12, 2024, and plaintiffs filed a supplemental complaint on June 13, 2024. On November 13, 2024, Plaintiffs filed a second motion to supplement their complaint. On March 13, 2024, plaintiffs filed a Motion for Class Certification. On February 25, 2025, the Texas District Court denied Plaintiff's motion for class certification without prejudice, explaining that rulings on pending motions, including specifically Plaintiffs' second motion to supplement their complaint, could affect disposition of class certification. On May 21, 2025, the Texas District Court granted Plaintiffs' second motion for leave to file a second supplemented complaint and instructed Plaintiffs to refile their motion for class certification. Plaintiffs filed their second supplemental complaint on May 22, 2025, and reasserted their motion for class certification on June 20, 2025. That motion is pending.

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 "CUNY Article"). 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 "Illinois District Court"). 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 Illinois District Court transferred this action to the Texas District Court, where it was consolidated into the Consolidated Securities Action.

The parties to the Consolidated Securities Action met for mediation in May 2025. The Company and the lead plaintiffs for the Consolidated Securities Action are in the advanced stages of settlement discussions. In light of these discussions, the Company has reserved a loss contingency of $31.25 million on its condensed consolidated balance sheet as of June 30, 2025 relating to a potential settlement of the Consolidated Securities Action.

The Company does not expect such settlement of the Consolidated Securities Action, if realized, to resolve the shareholder derivative actions or the 2024 Securities Class Action, each discussed below.

On November 4, 2021, a shareholder derivative action related to the initial four class action lawsuits filed in the Texas District Court was filed, purportedly on behalf of the Company, in the Texas District Court, 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 Texas District Court, 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 Texas District Court were consolidated into a single action. All of the foregoing derivative 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 Texas District Court. The parties to that case expect that it will be consolidated into the existing consolidated federal court shareholder derivative action.

Beginning on March 18, 2024, two shareholder derivative actions related to the February 2024 class action lawsuit originally filed in the Illinois District Court were filed, purportedly on behalf of the Company, in the Illinois District Court, 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 the CUNY Article. 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. On September 6, 2024, these two cases were consolidated and stayed pending further developments in the shareholder class action initially filed in the Illinois District Court on February 2, 2024.

Due to the stage of the foregoing shareholder derivative actions, the Company is unable to predict the outcome or estimate the amount of loss or range of losses that could potentially result from such derivative lawsuits.

On December 13, 2024, a putative class action lawsuit (the "2024 Securities Class Action") was filed, purportedly on behalf of the Company, alleging violations of the federal securities law by the Company and certain named officers. The complaint alleges that various statements made by the defendants regarding simufilam were revealed to be materially false and misleading by the release of top-line results for the Company's RETHINK-ALZ Phase 3 clinical trial on November 25, 2024. The 2024 Securities Class Action was filed in the Texas District Court. The complaint seeks unspecified compensatory damages and other relief on behalf of a purported class of purchasers of the Company's securities between February 7, 2024, and November 24, 2024. The Company believes that the likelihood of an unfavorable outcome is not probable, however, it is reasonably possible that the Company may incur a loss. The Company is unable to reasonably estimate the amount or range of potential loss at this time.

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 "CIB Derivative Action"). The complaint alleges, among other things, that the individual defendants breached their fiduciary duties by approving the CIB Plan in August 2020. The complaints sought 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 in the CIB Derivative Action entered into a Stipulation and Agreement of Settlement, Compromise, and Release (the "Stipulation") to resolve the CIB Derivative 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.

On June 26, 2024, the Delaware Court of Chancery entered the Scheduling Order, which included approval of the Notice. The Delaware Court of Chancery held a settlement hearing on September 9, 2024. On January 24, 2025, the Delaware Court of Chancery entered a Final Order and Judgment approving the Stipulation and dismissing the CIB Derivative Action with prejudice. Pursuant to the Final Order, the Company paid $1 million in attorneys' fees and expenses in February 2025, which was recorded in accounts payable and other accrued expenses at December 31, 2024.

Subject to the ongoing settlement discussions regarding the Consolidated Securities Action, the Company intends to defend all pending shareholder derivative actions and securities class actions vigorously.

Anti-SLAPP Lawsuit

On August 6, 2024, a lawsuit was filed in the District Court for the Southern District of New York which, as amended and as joined by intervenor plaintiffs, asserts claims, including a claim under the New York Anti-SLAPP Law, against the Company and against two former officers to whom the Company has certain indemnification obligations. The amended complaint and the complaint in intervention 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 has reached an agreement in principle to settle the claims brought by the intervenor plaintiffs and is negotiating a comprehensive settlement with mutual releases between the Company and the intervenor plaintiffs. The Company intends to defend vigorously the claims brought by the remaining plaintiffs. The Company has reserved a loss contingency of $4.0 million on its condensed consolidated balance sheet as of June 30, 2025 relating to potential settlement with the intervenor plaintiffs and other claimants.

Litigation Contingencies

In connection with ongoing litigation, the Company has reserved an amount of $35.25 million, including the $31.25 million loss contingency for the Consolidated Securities Action, for potential settlements at June 30, 2025. The Company recorded loss continencies totaling $32.25 million during the three months ended June 30, 2025. The Company recorded loss continencies totaling $35.25 million during the six months ended June 30, 2025. The Company believes that the likelihood of an unfavorable outcome is reasonably possible and has accrued this amount as the best estimate of potential loss. The final outcome of the litigation in which the Company is involved may differ from the reserved amount, and additional losses may be incurred.

Note 11. 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 exercise expenses and commissions.

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. As of September 30, 2024, there were no warrants outstanding.

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	—	$ —
Balance as of September 30, 2024	—	$ —
Balance as of December 31, 2024	—	$ —

There were no warrants outstanding at June 30, 2025.

Note 12. Restructuring Activities

On January 7, 2025, the Company announced a reduction in its workforce by 10 employees, a reduction of 33% (the “Workforce Reduction”). The Company communicated the Workforce Reduction to affected employees on January 7, 2025.

The Company incurred approximately $0.4 million of one-time costs in connection with the Workforce Reduction, primarily related to severance payments. The Company's Workforce Reduction was completed, and the associated costs and cash payments were made, during the first quarter of 2025.

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. 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 safety profile or treatment benefits, if any, of simufilam;
- our ability to conduct planned preclinical studies of simufilam relating to epilepsy in Tuberous Sclerosis Complex ("TSC")
- our plans to file an Investigational New Drug ("IND") application in respect of a proof-of-concept clinical trial for simufilam in TSC-related epilepsy
- our ability to initiate an initial proof-of-concept clinical study of simufilam in TSC-related epilepsy in first-half 2026
- our ability to initiate, conduct or analyze additional clinical and non-clinical studies with our product candidates targeted at central nervous system disorders, including TSC-related epilepsy;
- our ability to successfully carry out our obligations under our License Agreement with Yale, for which we have assumed all responsibility for global development and commercialization for simufilam for the treatment of TSC-related epilepsy;
- our plans or ability to expand therapeutic indications for simufilam outside of Alzheimer's disease;
- our reliance on third-party contractors to conduct all of our clinical and non-clinical trials and to make drug supply, or their ability to do so on-time or on-budget;
- limitations around the interpretation of data from any studies that are not randomized controlled trials;
- 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;
- 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 therapeutic areas we may elect to pursue;
- our need to raise new capital from time to time to finance our operations and the impact of macroeconomic conditions on our ability to effectively raise capital;
- 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, 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 ability to attract and retain personnel;
- existing or emerging regulations and regulatory developments in the United States and other jurisdictions in which we operate;
- our expectations regarding the appropriate 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;
- potential impacts of reductions-in-force at government agencies, including FDA, whose engagement with us in the drug development process is critical for the advancement of our investigational product candidates;
- the expense, timing and outcome of pending or future litigation or other legal proceedings and claims (including U.S. government inquiries) including the potential for negotiated settlements of such matters; and
- litigation, claims or other uncertainties that may arise from allegations made against us or our former employees or collaborators and the potential resolution of same.

Please also refer to the section entitled “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, as such risk factors may be further 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 undertake 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.

All our pharmaceutical assets under development are investigational product candidates. These have not been approved for use in any medical indication by any regulatory authority in any jurisdiction and their safety, efficacy or other desirable attributes, if any, have not been established in any patient population. Consequently, none of our product candidates are approved or available for sale anywhere in the world.

Our clinical results from earlier-stage clinical trials may not be indicative of future results from later-stage or larger scale clinical trials and do not ensure regulatory approval. You are cautioned that subsequent results may differ materially.

Overview

Cassava Sciences, Inc. is a clinical-stage biotechnology company based in Austin, Texas. Our mission is to detect and treat central nervous system disorders, such as Tuberous Sclerosis Complex (“TSC”)-related epilepsy. Our novel science is based on affecting the activity of a critical protein in the brain for patients with certain central nervous system disorders, such as TSC. Our lead therapeutic drug candidate, simufilam, was under clinical evaluation for the proposed treatment of Alzheimer’s disease in two Phase 3 clinical studies through 2024, when all ongoing clinical trials for simufilam in Alzheimer’s disease were discontinued. The phase out of the Company’s Alzheimer's disease development program was completed in the second quarter of 2025.

We combine innovative technology with new insights in neurobiology to develop novel solutions targeting central nervous system disorders, such as TSC-elated epilepsy. Our strategy is to leverage our unique scientific/clinical platform to develop first-in-class programs for treating central nervous system lisorders. In addition, we are in the early stages of exploring potential artificial intelligence (“AI”) capabilities and related data analytics to target improvements n productivity and efficiency in our business, enhancements to research and development activities, and advancements in statistical analysis capabilities.

Our lead therapeutic product candidate, called simufilam, is a proprietary small molecule oral treatment drug being studied for the treatment of TSC-related pilepsy.

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 a protein called filamin A (“FLNA”) in the brain of patients with central nervous system disorders, such as TSC. Our and our collaborators' published studies have demonstrated that changes in the expression or conformation of FLNA is linked to seizures, neuronal abnormalities, and neuroinflammation in certain circumstances and disorders. For example, published pre-clinical studies show that overexpression of FLNA in patients with TSC may be associated with neuronal abnormalities and epileptic seizure activity. On February 26, 2025, we entered into a License Agreement (the “License Agreement”) with Yale to support our development and commercialization efforts for simufilam for the treatment of TSC-related epilepsy.

We solely own patents covering the composition of matter of our drug simufilam in the United States, Europe, Australia, Israel and Canada. We solely own patents covering certain methods of use of our drug simufilam in the United States, Europe and Japan. We solely own pending patent applications that cover diagnostic assets for simufilam in the United States, Europe, Japan, China, Canada, and Australia. We solely own pending patent applications that cover other diagnostic assets in the United States, Europe, Japan, China and Canada. We have no obligation to pay any royalty to any third party in connection with any of the foregoing described patents and patent applications. In the United States, our patent protection with respect to simufilam, its solid forms, and uses of simufilam for Alzheimer’s disease and other neurodegenerative diseases includes nine issued United States patents, with terms expiring on dates ranging from 2029 to 2040, subject to any patent extensions that may be available for such patents. Corresponding foreign filings have been made for each of the Unites States filings.

About Tuberous Sclerosis Complex (TSC)

TSC is a genetic disorder that results from a mutation in the TSC1 or TSC2 genes. According to the Tuberous Sclerosis Alliance (“TSCA”), TSC is stimated to affect around 1 in 6,000 live births with approximately 50,000 people affected in the United States and more than one million worldwide. Clinical ymptoms of TSC are variable and can impact organ systems with non-malignant tumors developing in brain, eyes, heart, kidney, skin and lungs. Interrelated europsychiatric manifestations of TSC such as intellectual disability, autism spectrum disorder, anxiety, aggression, attention deficit hyperactivity disorder, and leep disturbance can significantly impact quality of life. Epilepsy is common in TSC, occurring in 84% of patients registered in the TSC Alliance Natural Iistory Database with onset often occurring in their first year of life. Approximately 60 percent of TSC patients suffer from treatment-resistant seizures despite

ıse of multiple anti-seizure medications. TSC-related epilepsy is associated with poor outcomes and increases the risk of cognitive deficits.

Preclinical Studies with Simufilam in Tuberous Sclerosis Complex

Preclinical research conducted at Yale indicates that simufilam (then PTI-125) may be effective in reducing TSC-related seizure activity. A study conducted by Angelique Bordey, PhD, at Yale and published in the peer-reviewed journal *Neuron* in 2014 found overexpression of FLNA and neuronal abnormalities in brain tissue from TSC patients, as well as in brain tissue from mice that had been genetically altered to model TSC. The study further found that genetically normalizing FLNA expression in the mice prevented neuronal abnormalities. The paper, MEK-ERK1/2-Dependent FLNA Overexpression Promotes Abnormal Dendritic Patterning in Tuberous Sclerosis Independent of mTOR (*Neuron*. 2014 Oct 1. PMID: 25277454), was co-authored by Zhang L, Bartley CM, Gong X, Hsieh LS, Lin TV and Feliciano DM.

A later study conducted by Dr. Bordey and published in the peer-reviewed journal *Science Translational Medicine* in 2020 likewise found elevated FLNA and neuronal abnormalities in brain tissue from patients with focal cortical dysplasia type II (FCDII), a genetic disorder with similar characteristics to TSC, as well as in the brains of mice that had been genetically altered to model TSC and FCDII. That study showed that normalizing FLNA expression in the mice through genetic knockdown both limited the neuronal abnormalities and reduced the frequency of epileptic seizures in the mice. This 2020 paper, Filamin A Inhibition Reduces Seizure Activity in a Mouse Model of Focal Cortical Malformations (*Sci Transl Med*. 2020 Feb 19. PMID: 32076941), was co-authored by Zhang L, Huang T, Teaw S, Nguyen LH, Hsieh LS, Gong X, and Lindsay Burns, a former employee of the Company.

In this 2020 study, Dr. Bordey and her colleagues also studied the effect of treatment with simufilam in the mice that had been altered to model TSC and FCDII. The research showed that treatment with simufilam limited neuronal abnormalities and reduced seizure activity in the mouse model at a level similar to genetic knockdown of FLNA expression. Treatment with simufilam did not, however, affect the level of FLNA in the brains of the mice.

Dr. Bordey joined the Company as Senior Vice President, Neuroscience, on May 1, 2025, while continuing her tenured academic position at Yale School of Medicine on a part time basis.

On August 4, 2025, the Company announced positive preclinical results of a study evaluating simufilam in a well-accepted mouse model of TSC-related epilepsy. The study was conducted in collaboration with the TSCA and the TSC Preclinical Consortium using an animal model of TSC-related epilepsy, the *Tsc1* conditional knockout (CKO) mouse line (*Tsc1*-CKO)[1]. These mice develop spontaneous seizures and are used by the TSC Alliance to evaluate the effectiveness and safety of novel and repurposed therapeutics in the potential treatment of TSC-related epilepsy. The study was conducted by PsychoGenics, Inc., the TSC Preclinical Consortium's research partner.

The *Tsc1*-CKO mice were treated with several doses of simufilam. Seizure activity was monitored for approximately three weeks after onset, and simufilam was evaluated against treatment with vehicle alone. The data showed that simufilam attenuated the progression of seizure activity, with a statistically significant correlation between simufilam dose and the number of seizures by the end of the study. Not all parameters measured reached statistical significance. The Company intends to present data and analyses in an upcoming scientific conference and publication.

Based on the results of these studies, the Company is planning to file an Investigational New Drug ("IND") application in order to initiate a proof-of-concept clinical trial for simufilam in TSC-related epilepsy. This first clinical study for simufilam in TSC-related epilepsy is expected to begin in first-half 2026. In connection with the initiation of this clinical program, the Company appointed Dr. Joseph Hulihan as Chief Medical Officer. Dr. Hulihan, who brings over 25 years of industry experience, will devote approximately half of his professional time to Cassava and will advise on this clinical development of simufilam.

License Agreement with Yale

On February 26, 2025, we entered into the License Agreement with Yale pursuant to which we were granted exclusive worldwide rights, with rights to sublicense, to Yale's interest in certain patent and other intellectual property rights that could be useful or necessary to the development and commercialization of simufilam for the treatment of TSC-related epilepsy and other potential indications. Pursuant to the License Agreement, we have agreed to use reasonable commercial efforts to implement a plan designed for such development and commercialization.

In exchange for the rights acquired pursuant to the License Agreement, we agreed to pay Yale (i) a nominal upfront license fee, (ii) payments upon the achievement of specified clinical, regulatory and commercial milestones, totaling up to $4.5 million and (iii) upon transfer to a third party of a regulatory priority review voucher, if issued, a low-to-mid double digit percentage of any consideration received for such transfer. We also agreed to pay Yale tiered royalties, ranging from a low- to mid- single digit percentage, on aggregate net sales of licensed products, subject to tiered minimum annual royalty payments ranging from the low- to mid- hundreds of thousands of dollars.

Unless earlier terminated, the License Agreement will continue on a country-by-country basis until the later of (i) the date on which the last valid claim of the license patents expires or otherwise lapses, (ii) the end of any government or regulatory exclusivity period, and (iii) 10 years following the date of first sale of licensed product in such country. We may terminate the License Agreement: (i) at our option, upon specified advance notice to Yale and (ii) if Yale commits a material breach of the License Agreement that is not cured within a specified timeframe. Yale may terminate the License Agreement under specified circumstances, including if we (i) fail to make any payment due under the License Agreement and fail to cure such non-payment within a specified timeframe, (ii) commit a breach of the License Agreement that is not cured within a specified timeframe, (iii) default on a material obligation to any creditor, unless cured within a specified timeframe, (iv) fail to obtain or maintain insurance required by the License Agreement, (v) bring or assist a patent challenge against Yale (or if a sublicensee does so). In addition, the License Agreement will terminate automatically upon the occurrence of certain bankruptcy and insolvency events involving us.

The License Agreement includes customary confidentiality, reporting and inspection, and indemnification provisions.

1. *https://www.tscalliance.org/researchers/preclinical-research/*

Clinical Trials in Alzheimer's Disease (Discontinued)

We have conducted two randomized placebo-controlled Phase 3 clinical trials of oral simufilam in patients with mild-to-moderate Alzheimer's disease. Our first Phase 3 study, called RETHINK-ALZ, was designed to evaluate the safety and efficacy of simufilam 100 mg tablets versus placebo over 52 weeks (NCT04994483). Our second Phase 3 study, called REFOCUS-ALZ, was designed to evaluate the safety and efficacy of oral simufilam 100 mg and 50 mg tablets versus placebo over 76 weeks (NCT05026177).

On November 25, 2024, we announced that the top-line results from the Phase 3 RETHINK-ALZ study of simufilam in mild-to-moderate Alzheimer's disease did not meet each of the pre-specified co-primary, secondary and exploratory biomarker endpoints. The co-primary endpoints were the change in cognition and function from baseline to the end of the double-blind treatment period at week 52, assessed by the ADAS-COG12 and ADCS-ADL scales, comparing simufilam to placebo. Simufilam continued to demonstrate an overall favorable safety profile.

In light of the top-line results from the Phase 3 RETHINK-ALZ study, the Company also discontinued the Phase 3 REFOCUS-ALZ study and Open Label Extension study.

On March 25, 2025, we announced that top-line results from the Phase 3 REFOCUS-ALZ study of simufilam in mild-to-moderate Alzheimer's disease did not meet each of the pre-specified co-primary, secondary and exploratory biomarker endpoints. The co-primary endpoints were the change in cognition and function from baseline to the end of the double-blind treatment period at week 76, assessed by the ADAS-COG12 and ADCS-ADL scales, comparing simufilam to placebo. REFOCUS-ALZ enrolled 1,125 patients and was discontinued on November 25, 2024, following the report that a prior 52-week Phase 3 study, RETHINK-ALZ, did not meet its co-primary endpoints. A large portion of subjects enrolled in REFOCUS-ALZ completed their final study visit prior to the termination of the trial. Simufilam continued to demonstrate an overall favorable safety profile.

Following the release of the topline RETHINK-ALZ and REFOCUS-ALZ results, the Company announced the decision to phase out the Company's Alzheimer's disease development program, which was completed in the second quarter of 2025.

Leadership Changes

Departure of Certain Executives

As previously announced, James W. Kupiec, M.D., retired as the Company's Chief Medical Officer, with his resignation effective as of May 9, 2025.

Appointment of Principal Operating Officer

On April 18, 2025, R. Christopher Cook, previously our Senior Vice President and General Counsel, was appointed Chief Operating and Legal Officer of the Company.

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 our 2024 Annual Report on Form 10-K and any subsequent Quarterly and Current Reports filed with the SEC in their entirety, including important disclosures under the caption "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.*

Our Scientific Approach is Different

Our scientific approach is to treat central nervous system diseases by targeting a scaffolding protein called FLNA. In light of existing research, we believe that FLNA is a promising target for drug development with respect to TSC-related epilepsy.

Research that we sponsored has identified a family of high-affinity, small molecules to target FLNA as a means of potentially treating central nervous system disorders such as TSC-related epilepsy. This family of small molecules, including simufilam, our lead small molecule (oral) therapeutic product candidate, was designed in-house and characterized by our academic collaborators.

Our science is based on affecting 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. When disease changes the shape and/or function of critical proteins, multiple downstream processes can be impaired. Restoring shape and/or function is a well-accepted therapeutic strategy in clinical medicine.

FLNA is a scaffolding protein found in the brain. A healthy scaffolding protein brings multiple proteins together, coordinating their interaction. Our product candidate, simufilam, targets FLNA and attempts to prevent abnormal functioning of this critical protein in diseases such as TSC.

We believe simufilam may present an opportunity to potentially reduce seizures in patients with TSC. Preclinical studies in a mouse model indicate that simufilam reduces seizure activity and limits neuronal abnormalities in a manner similar to genetically normalizing FLNA levels, but without lowering the level of FLNA in the brain.

Expansion of Our Science to Other Indications

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, initially focusing on central nervous system disorders. New indications and new drug development approaches may complement or supersede our current focus priorities.

We intend to continue exploratory preclinical studies in collaboration with the TSCA and other researchers to better understand simufilam's potential as a treatment for TSC-related seizures. The Company also intends to submit an IND application in respect of a proof-of-concept clinical trial for simufilam in TSC-related epilepsy.

REFOCUS-ALZ (Discontinued)

Our second Phase 3 study in Alzheimer's disease, called REFOCUS-ALZ, was 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 were randomized into this study.
- Patients were randomized (1:1:1) to simufilam 100 mg tablets, 50 mg tablets, or matching placebo twice daily.
- Patients that completed the trial prior to its early termination were treated for 76 weeks.
- Co-primary efficacy endpoints were change from baseline in the ADAS-Cog12, a cognitive scale, and the ADCS-ADL, a functional scale, each of which is a standard psychometric assessment tool in trials of Alzheimer's disease.
- A secondary efficacy endpoint was change from baseline in the iADRS, which is an integrated tool that combines scores from the ADAS-Cog12 and the ADCS-ADL.
- As in the RETHINK-ALZ trial, other secondary endpoints included change from baseline in NPI, MMSE, CDR-SB and ZBI.
- Additional secondary endpoints included sub-studies involving a limited number of patients and research sites to examine changes in baseline in:
  - plasma biomarkers of Alzheimer's Disease pathology, neurodegeneration and neuroinflammation (P-tau217, neurofilament light chain, known as NfL, glial fibrillary acidic protein, known as GFAP, and Total Tau);
  - cerebrospinal fluid (CSF) biomarkers of Alzheimer's Disease pathology, neurodegeneration and neuroinflammation;
  - brain volume—hippocampus, ventricles and whole brain—via magnetic resonance imaging (MRI); and
  - amyloid and tau deposition in the brain via positron emission topography (PET) imaging
- No interim analyses on efficacy were conducted.

The Company announced top-line results for REFOCUS-ALZ on March 25, 2025 as well as the decision to phase out the Company's Alzheimer's disease development program, which was completed in the second quarter of 2025.

Summary REFOCUS-ALZ Study Results:

Primary Endpoint Data

Co-Primary Endpoint Data*	Simufilam 100 mg BID	Simufilam 50 mg BID	Placebo BID	Delta	P-value
Co-Primary Endpoints LS means change from baseline to the end of the double-blind treatment period					
	N=372	**N=376**	**N=372**		
ADAS-COG12 (±SE)	4.97 (± 0.46)		4.70 (± 0.46)	0.27 (± 0.63)	P=0.67
		5.26 (± 0.46)	4.70 (± 0.46)	0.56 (± 0.63)	P=0.37
	N=373	**N=376**	**N=373**		
ADCS-ADL (±SE)	- 6.27 (± 0.57)		- 5.32 (± 0.57)	- 0.95 (± 0.79)	P=0.23
		- 6.43 (± 0.57)	- 5.32 (± 0.57)	- 1.10 (± 0.79)	P=0.16
*Based on the intent-to-treat population BID = twice daily ADAS-COG12 = The Alzheimer's Disease Assessment Scale – Cognitive Subscale (a lower number represents less cognitive impairment) ADCS-ADL = Alzheimer's Disease Cooperative Study – Activities of Daily Living (a higher number represents less functional impairment)					

Safety Data:

The table below provides a high-level summary of the patient demographic and safety data. Simufilam continued to demonstrate an overall favorable safety profile.

Metrics for Simufilam and Placebo	Simufilam 100 mg BID	Simufilam 50 mg BID	Placebo BID
Baseline*			
	N=374	**N=376**	**N=375**
Age, mean (SD), in years	73.6 ± 8.2	74.5 ± 7.6	73.7 ± 7.9
Sex, n (%) female	208 (55.6%)	207 (55.1%)	214 (57.1%)
MMSE Score (No.%,)			
21-27	240 (64.2%)	242 (64.4%)	235 (62.7%)
16-20	134 (35.8%)	134 (35.6%)	138 (36.8%)
Race/Ethnicity			
White	326 (87.2%)	326 (86.7%)	313 (83.5%)
Black	17 (4.5%)	23 (6.1%)	21 (5.6%)
Asian	28 (7.5%)	21 (5.6%)	32 (8.5%)
Other	3 (0.8%)	6 (1.6%)	9 (2.4%)
Safety**			
	N=374	**N=376**	**N=373**
Any Adverse Event (AE)	286 (76.5%)	288 (76.6%)	282 (75.6%)
Serious AEs	43 (11.5%)	61 (16.2%)	45 (12.1%)
Death	2 (0.5%)	6 (1.6%)	3 (0.8%)
AEs leading to discontinuation from the study	32 (8.6%)	34 (9.0%)	17 (4.6%)
Most Frequent AEs ≥ 5.0%			
1: COVID-19	45 (12.0%)	49 (13.0%)	40 (10.7%)
2: Urinary Tract Infection	32 (8.6%)	41 (10.9%)	34 (9.1%)
3: Fall	32 (8.6%)	43 (11.4%)	51 (13.7%)
4: Dizziness	26 (7.0%)	11 (2.9%)	23 (6.2%)
5: Diarrhea	14 (3.7%)	19 (5.1%)	15 (4.0%)
*Based on the intent-to-treat population **Based on the safety population BID = twice daily AD = Alzheimer's disease MMSE = Mini-Mental State Examination			

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 have discontinued the development of SavaDx as of mid-2025. SavaDx is a research-use only, non-safety related exploratory biomarker. Development activity related to SavaDx accounted for less than 1% of our research budget.

We Own Worldwide Rights to Our Development 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, maintain, and/or license intellectual property rights to technology for our development program.

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. We solely own patents covering the composition of matter of our drug simufilam in the United States, Europe, Australia, Israel and Canada. We solely own patents covering certain methods of use of our drug simufilam in the United States, Europe and Japan. We solely own pending patent applications that cover diagnostic assets for simufilam in the United States, Europe, Japan, China, Canada, and Australia. We solely own pending patent applications that cover other diagnostic assets in the United States, Europe, Japan, China and Canada. We have no obligation to pay any royalty to any third party in connection with any of the foregoing described patents and patent applications. In the United States, our patent protection with respect to simufilam, its solid forms, and uses of simufilam for Alzheimer's disease and other neurodegenerative diseases includes nine issued United States patents, with terms expiring on dates ranging from 2029 to 2040, subject to any patent extensions that may be available for such patents. Corresponding foreign filings have been made for each of the United States filings. We may also pursue additional intellectual property protections in other jurisdictions or in connection with any potential expansion into other indications, including other central nervous system disorders, such as TSC-related epilepsy, in each case, in light of the Company's overall strategic development plans.

On February 26, 2025, we entered into the License Agreement with Yale pursuant to which we were granted exclusive worldwide rights, with rights to sublicense, to Yale's interest in certain patent and other intellectual property rights that could be useful or necessary to the development and commercialization of simufilam for the treatment of TSC-related epilepsy and other potential indications.

Financial Overview

We have yet to generate any revenues from product sales. We have an accumulated deficit of $472.7 million at June 30, 2025. These losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs, legal 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:

- conduct preclinical and clinical studies for our product candidates, including simufilam for TSC-related epilepsy;
- 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; and
- expend resources related to legal proceedings and claims, including U.S. government inquiries.

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,	
	2025	2024	2025	2024
Clinical trials	$ 1,313	$ 10,877	$ 9,408	$ 22,169
Pre-clinical projects	827	867	1,542	1,999
Chemical, Manufacturing and Controls costs (“CMC costs”)	391	398	774	1,193
Personnel related	1,049	1,615	2,774	3,260
Stock-based compensation	1,162	972	3,534	1,945
Other	374	469	750	865
	$ 5,116	$ 15,198	$ 18,782	$ 31,431

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 in 2025 compared to 2024 as a result of phase out of our Alzheimer's disease development program, which was completed in the second quarter of 2025. The decrease is expected to be partially offset by costs to explore an indication for TSC-related epilepsy 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.

There have been no material changes to our critical accounting estimates during the six months ended June 30, 2025 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, 2024, as filed with the SEC on March 3, 2025.

Results of Operations – Three and Six Months Ended June 30, 2025 and 2024

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 $5.1 million and $15.2 million during the three months ended June 30, 2025 and 2024, respectively. This 66% decrease was due primarily to the phase out of the Alzheimer's disease development program, which was completed in the second quarter of 2025.

Research and development expenses were $18.8 million and $31.4 million during the six months ended June 30, 2025 and 2024, respectively. This 40% decrease was due primarily to the phase out of the Alzheimer's disease development program beginning the fourth quarter of 2024 and completed in the second quarter of 2025. This decrease was partially offset by a $1.6 million increase in stock-based compensation expense due to new awards granted in the third quarter of 2024.

We expect research and development expense to decrease in future periods now that the phase out of the Alzheimer's disease development program is complete, and expenses for the TSC-related epilepsy program are expected to be significantly lower compared to those for the Alzheimer's disease program.

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, public company compliance expenses and other administrative expenses and professional services.

General and administrative expenses were $40.3 million and $46.2 million during the three months ended June 30, 2025 and 2024, respectively. The 13% decrease was due primarily to a $40.0 million SEC-related loss contingency recorded in 2024, compared to a $31.3 million securities litigation loss contingency recorded in 2025. General and administrative expense in the second quarter of 2025 included approximately $3.6 million of legal related fees/costs as well as $3.4 million in non-cash stock based compensation expense.

General and administrative expenses were $51.2 million and $49.9 million during the six months ended June 30, 2025 and 2024, respectively. The 3% increase was due primarily to a $40.0 million SEC-related loss contingency recorded in 2024 being partially offset by $8.8 million in insurance recoveries. This compared to a $31.3 million securities litigation loss contingency recorded in 2025, for which there were no insurance recoveries. The change also included a $3.3 million increase in stock-based compensation expense due to new awards granted in late 2024.

We expect general and administrative expense will decrease significantly in future quarters. However, we expect general and administrative expense to remain high compared to historic levels due to professional fees, legal expense and potential settlements related to ongoing litigation. In addition, stock-based compensation expense is expected to be higher than historic levels due to new awards granted in 2024 and 2025.

Interest Income

Interest income was $1.2 million and $2.3 million during the three months ended June 30, 2025 and 2024, respectively. The decrease in interest income was due primarily to lower interest rates and cash balances in 2025 compared to 2024.

Interest income was $2.5 million and $4.1 million during the six months ended June 30, 2025 and 2024, respectively. The decrease in interest income was due primarily to lower interest rates and cash balances in 2025 compared to 2024.

We expect interest income to decrease in future quarters as we utilize cash in our operations and realize the impact of a lower interest rate environment.

Change in fair value of warrants

There were no common stock warrants outstanding or change in fair value of warrants for the three months ended June 30, 2025. The change in fair value of warrants was $65.1 million for the three months ended June 30, 2024.

There were no common stock warrants outstanding or change in fair value of warrants for the six months ended June 30, 2025. The change in fair value of warrants was $108.2 million for the six months ended June 30, 2024.

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 (loss), net, was $(46,000) and $0.1 million during the three months ended June 30, 2025 and 2024, respectively.

Other income (loss), net, was $(0.1) million and $0.3 million during the six months ended June 30, 2025 and 2024, respectively.

We recorded other loss in the three and six months ended June 30, 2025 as due to higher vacancy rates in 2025 compared to the prior year period. We expect other loss to increase in future periods due to the impact of higher vacancy rates on 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, 2025, cash and cash equivalents were $112.4 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 exercise expenses and commissions.

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.

2020 Cash Incentive Bonus Plan Obligations

Information with respect to the 2020 Cash Incentive Bonus Plan is included in Note 10 of "Notes to Condensed Consolidated Financial Statements" included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

No cash payments were authorized or made to participants under the CIB Plan as of June 30, 2025, or through the filing date of this Quarterly Report on Form 10-Q.

Use of Cash

Net cash used in operating activities was $16.3 million for the six months ended June 30, 2025, resulting primarily from a net loss of $67.6 million. This change was partially offset by an increase in accrued development expense of $1.3 million, an increase in accounts payable and accrued expenses of $35.2 million and a decrease in prepaid and other current assets of $5.5 million. There was also a non-cash adjustment for stock-based compensation expense of $9.8 million.

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.

There was no net cash used in investing activities during the six months ended June 30, 2025.

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

Net cash provided by financing activities during the six months ended June 30, 2025 was $0.1 million of proceeds from the exercise of stock options.

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.

Property and Leases

We own an office complex in Austin, Texas, a portion of which serves as our corporate headquarters. 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, 2025, we occupied approximately 25% of the property with the remainder either leased or available for lease to third parties. Most tenant leases expired in 2024. We expect to record a net loss on leasing activities in 2025 as the higher vacancy rates are expected to significantly lower rental income.

Other Commitments

We have an accumulated deficit of $472.7 million as of June 30, 2025. 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***

As a smaller reporting company, per Item 305(e) of Regulation S-K, we are not required to provide the information called for by this Item 3.

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

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

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2025, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting. There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified during the three months ended June 30, 2025 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 except as disclosed in this Quarterly Report on Form 10-Q in Note 10 to our condensed consolidated financial statements entitled, "Contingencies.". 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 the "Contingencies" note.

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

Please refer to "Risk Factors" in Part I, Item 1A of our 2024 Annual Report on Form 10-K for additional information on our current risks. Other than the supplemental risk factor 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 2024 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.

Disruptions at FDA, including due to a reduction in FDA's workforce and/or inadequate funding for FDA, could prevent FDA from performing normal functions on which our business relies, which could negatively impact our business.

The ability of FDA to review and approve new products or review other regulatory submissions can be affected by a variety of factors, including statutory, regulatory and policy changes, inadequate government budget and funding levels, a reduction in FDA's workforce and its ability to hire and retain key personnel. Disruptions at FDA and other agencies may also increase the time to meet with and receive agency feedback, review and/or approve our submissions, conduct inspections, issue regulatory guidance, or take other actions that facilitate the development, approval and marketing of regulated products, which would adversely affect our business. In addition, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to

FDA and other related government agencies. For example, in March 2025, the U.S. Department of Health and Human Services (HHS) announced a significant restructuring, which included an FDA workforce reduction of approximately 3,500 employees. It is unclear how existing or planned executive and administrative actions designed to streamline governmental operations and centralize administrative functions will impact FDA or other regulatory authorities that oversee our business. Although the reductions at FDA announced in March 2025 did not target drug and medical device reviewers, such reductions or future reductions in FDA's workforce as well as budgetary pressures could nevertheless significantly impact the ability of FDA to timely review and process our regulatory submissions or take other actions critical to the development of our products which could have a material adverse effect on our business.

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, 2025, 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	
10.1*	Amended and Restated Employment Agreement, dated April 18, 2025, by and between Cassava Sciences, Inc. and Eric J. Schoen	8-K	4/21/2025	10.3	
10.2*	Amended and Restated Employment Agreement, dated April 18, 2025, by and between Cassava Sciences, Inc. and R. Christopher Cook	8-K	4/21/2025	10.2	
10.4*	Cassava Sciences, Inc. 2020 Cash Incentive Bonus Plan (As Amended and Restated on March 6, 2025)	8-K	3/11/2025	10.1	
10.5†	License Agreement, dated February 26, 2025, by and between Cassava Sciences, Inc. and Yale University.	8-K	2/27/2025	10.1	
10.6*	Cassava Sciences, Inc. Amended Non-employee Director Compensation Program	8-K	5/27/2025	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

* Management contract, compensatory plan or arrangement.

† Certain portions of this exhibit (indicated by "[***]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both not material and is the type of information that the Registrant treats as private or confidential.

+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,
President and Chief Executive Officer
Date: August 14, 2025 (Principal Executive Officer)

/s/ ERIC J. SCHOEN
Eric J. Schoen,
Chief Financial Officer
Date: August 14, 2025 (Principal Financial and Accounting Officer)

Exhibit 31.1

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,
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 14, 2025

Exhibit 31.2

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 14, 2025

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

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

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2025, 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 14, 2025

/s/ RICHARD J. BARRY
Richard J. Barry
President and Chief Executive Officer
(Principal Executive Officer)

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