

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 September 30, 2023
or

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

For the Transition Period from _____
to _____

Commission File Number: 000-29959

Cassava Sciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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
Non-accelerated Filer

Accelerated Filer
Smaller Reporting Company
Emerging Growth Company

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

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

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

Common Stock, \$0.001 par value

42,174,062

Shares Outstanding as of November 2, 2023

CASSAVA SCIENCES, INC.
TABLE OF CONTENTS

	<u>Page No.</u>
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements	
Condensed Consolidated Balance Sheets – September 30, 2023 and December 31, 2022	3
Condensed Consolidated Statements of Operations – Three and Nine Months Ended September 30, 2023 and 2022	4
Condensed Consolidated Statements of Changes in Stockholders' Equity - Three and Nine Months Ended September 30, 2023 and 2022	5
Condensed Consolidated Statements of Cash Flows – Nine Months Ended September 30, 2023 and 2022	6
Notes to Condensed Consolidated Financial Statements	7
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	18
Item 3. Quantitative and Qualitative Disclosures About Market Risk	35
Item 4. Controls and Procedures	36
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	36
Item 1A Risk Factors	37
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	37
Item 3. Defaults Upon Senior Securities	37
Item 4. Mine Safety Disclosures	38
Item 5. Other Information	38
Item 6. Exhibits	39
Signatures	40

PART I. FINANCIAL INFORMATION**Item 1. Financial Statements****CASSAVA SCIENCES, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**
(Unaudited, In thousands, except share and par value data)

	September 30,	December 31,
	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 142,350	\$ 201,015
Prepaid expenses and other current assets	7,834	10,211
Total current assets	150,184	211,226
Operating lease right-of-use assets	—	122
Property and equipment, net	22,077	22,864
Intangible assets, net	268	622
Total assets	<u>\$ 172,529</u>	<u>\$ 234,834</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,492	\$ 4,017
Accrued development expense	7,344	2,280
Accrued compensation and benefits	187	170
Operating lease liabilities, current	—	104
Other current liabilities	391	492
Total current liabilities	17,414	7,063
Operating lease liabilities, non-current	—	35
Other non-current liabilities	—	197
Total liabilities	17,414	7,295
Commitments and contingencies (Notes 9, 10 and 11)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized, none issued and outstanding	—	—
Common stock, \$0.001 par value; 120,000,000 shares authorized; 42,129,798 and 41,735,557 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	42	42
Additional paid-in capital	514,923	511,049
Accumulated deficit	(359,850)	(283,552)
Total stockholders' equity	155,115	227,539
Total liabilities and stockholders' equity	<u>\$ 172,529</u>	<u>\$ 234,834</u>

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		Nine months ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development, net of grant reimbursement	\$ 23,603	\$ 18,526	\$ 70,692	\$ 50,380
General and administrative	4,276	2,819	12,476	8,703
Total operating expenses	27,879	21,345	83,168	59,083
Operating loss	(27,879)	(21,345)	(83,168)	(59,083)
Interest income	2,005	878	6,254	1,223
Other income, net	223	210	616	748
Net loss	\$ (25,651)	\$ (20,257)	\$ (76,298)	\$ (57,112)
Net loss per share, basic and diluted	\$ (0.61)	\$ (0.51)	\$ (1.82)	\$ (1.43)
Shares used in computing net loss per share, basic and diluted	42,002	40,050	41,845	40,009

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	Accumulated	Total
	Shares	Par value	paid-in capital	deficit	stockholders' equity
Balance at December 31, 2021	40,016,792	\$ 40	\$ 461,181	\$ (207,306)	\$ 253,915
Stock-based compensation for:					
Stock options for employees	—	—	471	—	471
Stock options for non-employees	—	—	24	—	24
Issuance of common stock pursuant to exercise of stock options	14,488	—	211	—	211
Net loss	—	—	—	(17,527)	(17,527)
Balance at March 31, 2022	<u>40,031,280</u>	<u>\$ 40</u>	<u>\$ 461,887</u>	<u>\$ (224,833)</u>	<u>\$ 237,094</u>
Stock-based compensation for:					
Stock options for employees	—	—	462	—	462
Stock options for non-employees	—	—	23	—	23
Issuance of common stock pursuant to exercise of stock options	66,637	—	119	—	119
Net loss	—	—	—	(19,328)	(19,328)
Balance at June 30, 2022	<u>40,097,917</u>	<u>\$ 40</u>	<u>\$ 462,491</u>	<u>\$ (244,161)</u>	<u>\$ 218,370</u>
Stock-based compensation for:					
Stock options for employees	—	—	447	—	447
Stock options for non-employees	—	—	23	—	23
Expiration of restricted stock Performance Awards	(57,143)	—	—	—	—
Issuance of common stock pursuant to exercise of stock options	18,740	—	136	—	136
Net loss	—	—	—	(20,257)	(20,257)
Balance at September 30, 2022	<u>40,059,514</u>	<u>\$ 40</u>	<u>\$ 463,097</u>	<u>\$ (264,418)</u>	<u>\$ 198,719</u>
Balance at December 31, 2022	41,735,557	\$ 42	\$ 511,049	\$ (283,552)	\$ 227,539
Stock-based compensation for:					
Stock options for employees	—	—	650	—	650
Stock options for non-employees	—	—	23	—	23
Issuance of common stock pursuant to exercise of stock options	13,878	—	64	—	64
Net loss	—	—	—	(24,271)	(24,271)
Balance at March 31, 2023	<u>41,749,435</u>	<u>\$ 42</u>	<u>\$ 511,786</u>	<u>\$ (307,823)</u>	<u>\$ 204,005</u>
Stock-based compensation for:					
Stock options for employees	—	—	812	—	812
Stock options for non-employees	—	—	23	—	23
Issuance of common stock pursuant to exercise of stock options	170,092	—	889	—	889
Net loss	—	—	—	(26,376)	(26,376)
Balance at June 30, 2023	<u>41,919,527</u>	<u>\$ 42</u>	<u>\$ 513,510</u>	<u>\$ (334,199)</u>	<u>\$ 179,353</u>
Stock-based compensation for:					
Stock options for employees	—	—	926	—	926
Stock options for non-employees	—	—	23	—	23
Issuance of common stock pursuant to exercise of stock options	210,271	—	464	—	464
Net loss	—	—	—	(25,651)	(25,651)
Balance at September 30, 2023	<u>42,129,798</u>	<u>\$ 42</u>	<u>\$ 514,923</u>	<u>\$ (359,850)</u>	<u>\$ 155,115</u>

See accompanying notes to condensed consolidated financial statements.

CASSAVA SCIENCES, INC.

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

	Nine months ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (76,298)	\$ (57,112)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,457	1,450
Depreciation	817	533
Amortization of intangible assets	357	379
Changes in operating assets and liabilities:		
Prepaid and other current assets	2,377	2,790
Operating lease right-of-use assets and liabilities	(17)	(6)
Accounts payable and accrued expenses	5,815	(3,592)
Accrued development expense	5,064	1,293
Accrued compensation and benefits	17	(1,717)
Other liabilities	(298)	(212)
Net cash used in operating activities	<u>(59,709)</u>	<u>(56,194)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(373)	(3,047)
Net cash used in investing activities	<u>(373)</u>	<u>(3,047)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of stock options	1,417	466
Net cash provided by financing activities	<u>1,417</u>	<u>466</u>
Net decrease in cash and cash equivalents	(58,665)	(58,775)
Cash and cash equivalents at beginning of period	201,015	233,437
Cash and cash equivalents at end of period	<u>\$ 142,350</u>	<u>\$ 174,662</u>

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”) discover and develop 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 nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for any other interim period or for the year 2023. 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, 2022.

Liquidity

The Company has incurred significant net losses and negative cash flows since inception, and as a result has an accumulated deficit of \$359.9 million at September 30, 2023. The Company expects its cash requirements to be significant in the future. The amount and timing of the Company’s future cash requirements will depend on regulatory and market acceptance of its product candidates and the resources it devotes to researching and developing, formulating, manufacturing, commercializing and supporting its products. The Company may seek additional funding through public or private financing in the future, if such funding is available and on terms acceptable to the Company. There are no assurances that additional financing will be available on favorable terms, or at all. However, management believes that the current working capital position will be sufficient to meet the Company’s working capital needs for at least the next 12 months.

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

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

Cash and Cash Equivalents and Concentration of Credit Risk

The Company invests in cash and cash equivalents. The Company considers highly liquid financial instruments with original maturities of three months or less to be cash equivalents. Highly liquid investments that are considered cash equivalents include money market accounts and funds, certificates of 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 September 30, 2023 and December 31, 2022.

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.

Proceeds from Grants

During the three and nine months ended September 30, 2023, there were no reimbursements received pursuant to National Institutes of Health ("NIH") research grants. During the three and nine months ended September 30, 2022, the Company received reimbursements totaling \$0.4 million and \$0.9 million, respectively, pursuant to NIH research grants. The Company records the proceeds from these grants as reductions to its research and development expenses.

Stock-based Compensation

The Company recognizes non-cash expense for the fair value of all stock options and other share-based awards. The Company uses the Black-Scholes option valuation model to calculate the fair value of stock options, using the single-option award approach and straight-line attribution method. This model requires the input of subjective assumptions including expected stock price volatility, expected life and estimated forfeitures of each award. These assumptions consist of estimates of future market conditions, which are inherently uncertain, and therefore, are subject to management's judgment. For all options granted, it recognizes the resulting fair value as expense on a straight-line basis over the vesting period of each respective stock option, generally four years.

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

Net Loss per Share

The Company computes basic net loss per share on the basis of the weighted-average number of common shares outstanding for the reporting period. Diluted net loss per share is computed on the basis of the weighted-average number of common shares outstanding plus potential dilutive common shares outstanding using the treasury-stock method. Potential dilutive common shares consist of outstanding common stock options. There is no difference between the Company's net loss and comprehensive 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 September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net loss	\$ (25,651)	\$ (20,257)	\$ (76,298)	\$ (57,112)
Denominator:				
Shares used in computing net loss per share, basic and diluted	42,002	40,050	41,845	40,009
Net loss per share, basic and diluted	<u>\$ (0.61)</u>	<u>\$ (0.51)</u>	<u>\$ (1.82)</u>	<u>\$ (1.43)</u>
Dilutive common stock options excluded from net loss per share, diluted	1,780	1,946	1,938	2,064

The Company excluded common stock options outstanding from the calculation of net loss per share, diluted, because the effect of including outstanding options would have been anti-dilutive. The Company also excluded 57,143 restricted stock awards from the calculation of net loss per share, diluted, until their expiration in June 2022 because the effect of including restricted stock awards would have been anti-dilutive.

Fair Value of Financial Instruments

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

Research Contract Costs and Accruals

The Company has entered into various research and development contracts with research institutions and other third-party vendors. These agreements are generally cancelable. 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 "Plan") to incentivize Plan participants. Awards under the Plan are accounted for as liability awards under Accounting Standards Codification (ASC) 718 "Stock-based Compensation". The fair value of each potential Plan award will be determined once a grant date occurs and will be remeasured each reporting period. Compensation expense associated with the Plan will be recognized over the expected achievement period for each Plan award, when a Performance Condition (as defined below) is considered probable of being met. See Note 10 for further discussion of the Plan.

Leases

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

Property and equipment

Property and equipment are recorded at cost, net of accumulated depreciation. Depreciation is recorded using the straight-line method over the estimated useful lives of the assets. Owned buildings and related improvements have estimated useful lives of 39 years and approximately 10 years, respectively. Tenant improvements are amortized using the straight-line method over the useful lives of the improvements or the remaining term of the corresponding leases, whichever is shorter. The remaining term of the corresponding leases is approximately 0.6 years.

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

Intangible assets

Acquired intangible assets are recorded at fair value at the date of acquisition and primarily consist of lease-in-place agreements and leasing commissions. Intangible assets are amortized over the estimated life of the lease-in-place agreements, which is approximately 0.5 years at September 30, 2023.

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

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.

Note 3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets at September 30, 2023 and December 31, 2022 consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Prepaid insurance	\$ 1,136	\$ 874
Contract research organization and other deposits	5,224	9,177
Interest receivable	1,285	—
Other	189	160
Total prepaid expenses and other current assets	<u>\$ 7,834</u>	<u>\$ 10,211</u>

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

Note 4. Real Property

The Company owns a two-building office complex in Austin, Texas, a portion of which serves as its corporate headquarters. This property is intended to accommodate the Company's anticipated growth and expansion of its operations in the coming years. Maintenance, physical facilities, leasing, property management and other key responsibilities related to property ownership are outsourced to professional real-estate managers. The office complex has approximately 90,000 square feet of rentable space. At September 30, 2023, the property was over 60% leased. The Company also occupies approximately 25% of the property.

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 are 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 September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Lease revenue	\$ 583	\$ 620	\$ 1,699	\$ 1,780
Property operating expenses	(360)	(410)	(1,083)	(1,032)
Other income, net	<u>\$ 223</u>	<u>\$ 210</u>	<u>\$ 616</u>	<u>\$ 748</u>

Note 5. Property and equipment

The components of property and equipment, net, as of September 30, 2023 and December 31, 2022 were as follows (in thousands):

	September 30, 2023	December 31, 2022
Land	\$ 3,734	\$ 3,734
Buildings	15,980	15,980
Site improvements	494	470
Tenant improvements	3,018	3,016
Furniture and equipment	868	851
Construction in progress	—	13
Gross property and equipment	\$ 24,094	\$ 24,064
Accumulated depreciation	(2,017)	(1,200)
Property and equipment, net	\$ 22,077	\$ 22,864

Depreciation expense for property and equipment was \$273,000 and \$181,000 for the three months ended September 30, 2023 and 2022, respectively. Depreciation expense for property and equipment was \$817,000 and \$533,000 for the nine months ended September 30, 2023 and 2022, respectively.

Note 6. Intangible assets

The components of intangible assets, net, as of September 30, 2023 and December 31, 2022 were as follows (in thousands):

	September 30, 2023	December 31, 2022
Lease-in-place agreements	\$ 1,053	\$ 1,053
Leasing commissions and other	293	290
Gross intangible assets	\$ 1,346	\$ 1,343
Accumulated amortization	(1,078)	(721)
Intangible assets, net	\$ 268	\$ 622

Amortization expense for intangible assets was \$119,000 for the three months ended September 30, 2023 and 2022. Amortization expense for intangible assets was \$357,000 and \$379,000 for the nine months ended September 30, 2023 and 2022, respectively.

Amortization expense for finite-lived intangible assets as of September 30, 2023 is expected to be as follows (in thousands):

For the year ending December 31,

2023	\$ 97
2024	167
2025	4
Total amortization	\$ 268

Note 7. Stockholders' Equity and Stock-Based Compensation Expense***2022 Registered Direct Offering***

On November 22, 2022, the Company completed a common stock offering pursuant to which certain investors purchased 1,666,667 shares of common stock at a price of \$30.00 per share. Net proceeds of the offering were approximately \$47.3 million after deducting offering expenses.

At-the-Market Common Stock Offering

On May 1, 2023, the Company entered into an at-the-market offering program (“ATM”) to sell, from time to time, shares of Company common stock having an aggregate offering price of up to \$200 million in common stock pursuant to a shelf registration statement that was filed with the U.S. Securities and Exchange Commission (the “SEC”) on May 1, 2023 and became effective immediately upon filing. The Company is obligated to pay a commission of up to 3% of the gross proceeds from the sale of shares of common stock in the offering. The Company is not obligated to sell any shares in the offering.

There were no common stock sales under the ATM during the three and nine months ended September 30, 2023.

In March 2020, the Company entered into an at-the-market offering program (“2020 Program”) to sell, from time to time, shares of Company common stock having an aggregate offering price of up to \$100 million in transactions pursuant to a shelf registration statement that was declared effective by the SEC on May 5, 2020. The Company gave notice of termination for the 2020 Program on April 26, 2023, which was effective May 1, 2023. There were no common stock sales under the 2020 Program through its termination.

Stock Option and Performance Award Activity in 2023

During the nine months ended September 30, 2023, 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, 2022	2,529,448	7,142
Options granted	132,000	—
Options exercised	(495,299)	—
Options forfeited/canceled	(7,142)	—
Outstanding as of September 30, 2023	<u>2,159,007</u>	<u>7,142</u>

The weighted average exercise price per share of options outstanding at September 30, 2023 was \$13.71. As outstanding options vest over the current remaining vesting period of 2.3 years, the Company expects to recognize stock-based compensation expense of \$8.0 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 September 30, 2023, there were 214,124 stock options exercised. Of the stock options exercised, 3,853 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 \$464,000 during the three months ended September 30, 2023.

During the nine months ended September 30, 2023, there were 495,299 stock options exercised. Of the stock options exercised, 101,058 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 \$1,417,000 during the nine months ended September 30, 2023.

Subsequent to September 30, 2023, there were 800,000 stock options granted to officers and employees at an exercise price of \$17.54 per share.

Stock-based Compensation Expense in 2023

During the three and nine months ended September 30, 2023 and 2022, the Company’s stock-based compensation expense was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Research and development	\$ 405	\$ 399	\$ 1,186	\$ 1,234
General and administrative	544	70	1,271	216
Total stock-based compensation expense	<u>\$ 949</u>	<u>\$ 469</u>	<u>\$ 2,457</u>	<u>\$ 1,450</u>

2018 Equity Incentive Plan

The Company's Board of Directors (the "Board") or a designated committee of the Board is responsible for administration of the Company's 2018 Omnibus Incentive Plan, as amended (the "2018 Plan") and determines the terms and conditions of each option granted, consistent with the terms of the 2018 Plan. The Company's employees, directors, and consultants are eligible to receive awards under the 2018 Plan, including grants of stock options and Performance Awards. Share-based awards generally expire 10 years from the date of grant. The 2018 Plan, as amended on May 5, 2022, provides for issuance of up to 5,000,000 shares of common stock, par value \$0.001 per share, subject to adjustment as provided in the 2018 Plan.

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

Note 8. Income Taxes

The Company did not provide for income taxes during the three and nine months ended September 30, 2023, because it has projected a net loss for the full year 2023 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 nine months ended September 30, 2022.

Note 9. Commitments

Right-of-use Asset and Liability

The Company had an operating lease for approximately 6,000 square feet of office space in Austin, Texas with an expiration of April 30, 2024. The Company and the landlord consented to early terminate this lease on February 22, 2023 with no continuing obligations.

There was no rent expense for the three months ended September 30, 2023. Rent expense for the three months ended September 30, 2022 totaled \$41,000.

Rent expense for the nine months ended September 30, 2023 and 2022 totaled \$24,000 and \$123,000, respectively.

There was no cash paid for operating lease liabilities during the three months ended September 30, 2023. Cash paid for operating lease liabilities during the three months ended September 30, 2022 totaled \$41,000.

Cash paid for operating lease liabilities during the nine months ended September 30, 2023 and 2022 totaled \$24,000 and \$124,000, respectively.

Other Commitments

The Company conducts its product research and development programs through a combination of internal and collaborative programs that include, among others, arrangements with universities, contract research organizations and clinical research sites. The Company has contractual arrangements with these organizations that are cancelable. The Company's obligations under these contracts are largely based on services performed.

Note 10. 2020 Cash Incentive Bonus Plan

In August 2020, the Board approved the Plan. The Plan was established to promote the long-term success of the Company by creating an "at-risk" cash bonus program that rewards Plan participants with additional cash compensation in lockstep with significant increases in the Company's market capitalization. The Plan is considered "at-risk" because Plan participants will not receive a cash bonus unless the Company's market capitalization increases significantly and certain other conditions specified in the Plan are met. Specifically, Plan participants will not be paid any cash bonuses unless (1) the Company completes a merger or acquisition transaction that constitutes a sale of ownership of the Company or its assets (a "Merger Transaction") or (2) the Compensation Committee of the Board (the "Compensation Committee") determines the Company has sufficient cash on hand, as defined in the Plan. Because of the inherent discretion and uncertainty regarding these requirements, the Company has concluded that a Plan grant date has not occurred as of September 30, 2023.

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

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

The Company's market capitalization for purposes of the 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 Plan triggers a potential cash bonus each time the Company's market capitalization increases significantly, up to a maximum \$5 billion in market capitalization. The Plan specifies 14 incremental amounts between \$200 million and \$5 billion (each increment, a "Valuation Milestone"). Each Valuation Milestone triggers a potential cash bonus award in a pre-set amount defined in the Plan. Each Valuation Milestone must be achieved and maintained for no less than 20 consecutive trading days for Plan participants to be eligible for a potential cash bonus award. Approximately 67% of each cash bonus award associated with a Valuation Milestone is subject to adjustment and approval by the Compensation Committee. Any amounts not awarded by the Compensation Committee are no longer available for distribution.

If the Company were to exceed a \$5 billion market capitalization for no less than 20 consecutive trading days, all Valuation Milestones would be deemed achieved, in which case cash bonus awards would range from a minimum of \$111.4 million up to a hypothetical maximum of \$289.7 million. Payment of cash bonuses is deferred until such time as (1) the Company completes a Merger Transaction, or (2) the Compensation Committee determines the Company has sufficient cash on hand to render payment (each, a "Performance Condition"), neither of which may ever occur. Accordingly, there can be no assurance that Plan participants will ever be paid a cash bonus that is awarded under the Plan, even if the Company's market capitalization increases significantly.

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

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

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

No Valuation Milestones were achieved during 2022 or the nine months ended September 30, 2023.

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

Note 11. Contingencies

From time to time, the Company may become involved in litigation or other legal proceedings and claims, including U.S. government inquiries, investigations and Citizen Petitions submitted to FDA, and 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. No information is available to indicate that it is probable that a loss has been incurred or can be reasonably estimated as of the date of the condensed consolidated financial statements and, as such, no accrual for these matters has been recorded within the condensed consolidated financial statements.

Government Investigations

On November 15, 2021, the Company disclosed that certain government agencies had asked the Company to provide corporate information and documents. These were confidential requests. The Company has been voluntarily cooperating and intends to continue to cooperate with these inquiries. No government agency has informed the Company that it has found evidence of research misconduct or wrongdoing by the Company or its officers, employees or directors. No government agency has filed any claims or charges relating to these inquiries. We cannot predict the outcome or impact of these ongoing matters, including whether a government agency may pursue an enforcement action against the Company or others.

Securities Class Actions and Shareholder Derivative Actions

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

On June 30, 2022, a federal judge consolidated the four class action lawsuits into one case and appointed a lead plaintiff and a lead counsel. Lead plaintiff filed a consolidated amended complaint on August 18, 2022 on behalf of a putative class of purchasers of the Company's securities between September 14, 2020 and July 26, 2022. On May 11, 2023, the court dismissed with prejudice plaintiffs' claims against defendant Nadav Friedmann, PhD, MD, our former Chief Medical Officer and a Company director, who is now deceased, but otherwise denied defendants' motion to dismiss. Defendants filed an answer to the consolidated amended complaint on July 3, 2023. The Company believes the claims are without merit and intends to defend against these lawsuits vigorously. The Company is unable to estimate the possible loss or range of loss, if any, associated with these lawsuits.

On November 4, 2021, a related shareholder derivative action was filed, purportedly on behalf of the Company, in the U.S. District Court for the Western District of Texas, asserting claims under the U.S. securities laws and state fiduciary duty laws against certain named officers and the members of the Company's Board. This complaint relies on the allegations made in Citizen Petitions that were submitted to (and subsequently denied by) FDA. The complaint alleges, among other things, that the individual defendants exposed the Company to unspecified damages and securities law liability by causing it to make materially false and misleading statements, in violation of the U.S. securities laws and in breach of their fiduciary duties to the Company. The derivative case seeks, among other things, to recover unspecified compensatory damages on behalf of the Company arising out of the individual defendant's 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. Since November 4, 2021, four additional shareholder derivative actions were filed alleging substantially similar claims, two in the U.S. District Court for the Western District of Texas, one in Texas state court (Travis County District Court) and one in the Delaware Court of Chancery. On July 5, 2022, the three federal court actions were consolidated into a single action.

On August 19, 2022, a shareholder derivative action was filed, purportedly on behalf of the Company, in the Delaware Court of Chancery, asserting claims under state fiduciary duty laws against certain named officers and members of the Company's Board. The complaint alleges, among other things, that the individual defendants breached their fiduciary duties by approving the 2020 Cash Incentive Bonus Plan in August 2020. The complaints seek unspecified compensatory damages and other relief. On January 6, 2023, the plaintiffs filed an amended complaint. Defendants filed a partial answer to the amended complaint on March 10, 2023, and moved to partially dismiss the amended complaint on March 14, 2023. Defendants' motion to dismiss remains pending. Although the plaintiffs in this derivative case do not seek relief against the Company, the Company has certain indemnification obligations to the individual defendants.

The Company is unable to estimate the possible loss or range of loss, if any, associated with these lawsuits.

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.

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

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

- the expected safety profile or treatment benefits of simufilam for people with Alzheimer's disease in our on-going Phase 3 studies;
- our reliance on third-party contractors to conduct the clinical trials and make drug supply on a large-scale for our Phase 3 clinical program, or their ability to do so on-time or on-budget;
- limitations around data interpretation from results of our Cognition Maintenance Study (CMS) and long-term open-label study, as compared to efficacy results from a fully completed Phase 3 clinical program;
- the ability of clinical scales to assess cognition or health in our trials of Alzheimer's disease;
- any significant changes we may make, or anticipate making, to the design of any of our on-going studies of simufilam in patients with Alzheimer's disease;
- our ability to initiate, conduct or analyze additional clinical and non-clinical studies with our product candidates targeted at Alzheimer's disease and other neurodegenerative diseases;
- the impact of pre-clinical findings on our ability to develop our product candidates;
- the interpretation of results from our pre-clinical or early clinical studies, such as Phase 1 and Phase 2 studies;
- our plans to further develop SavaDx, our investigational blood-based diagnostic, and to evaluate a non-antibody approach for SavaDx;
- our ability or willingness to expand therapeutic indications for simufilam outside of Alzheimer's disease;
- the safety, efficacy, or potential therapeutic benefits of our product candidates;
- our ability to file for and obtain regulatory approval of our product candidates;
- our strategy and ability to establish an infrastructure to commercialize any product candidates, if approved;
- the potential future revenues of our product candidates, if approved and commercialized;
- the market acceptance of our product candidates, if approved and commercialized;
- the pricing and reimbursement of our product candidates, if approved and commercialized;
- the utility of protection, or the sufficiency, of our intellectual property;
- our potential competitors or competitive products for the treatment of Alzheimer's disease;
- our need to raise new capital from time to time to continue our operations or to expand our operations;
- our use of multiple third-party vendors, including a Clinical Research Organization (CRO), to conduct clinical studies of our lead product candidate;
- expectations regarding trade secrets, technological innovations, licensing agreements and outsourcing of certain business functions;
- our expenses increasing by unanticipated amounts due to inflation;
- 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 need to hire additional personnel and our ability to attract and retain such personnel;
- existing regulations and regulatory developments in the United States and other jurisdictions in which we operate;
- our plans to expand the size and scope of our operations;
- the sufficiency of our current 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, capital requirements, and needs for additional financing;
- assumptions and estimates used for our disclosures regarding stock-based compensation;
- the expense, timing and outcome of pending or future litigation or other legal proceedings and claims, including government inquiries; and
- litigation, claims or other uncertainties that may arise from allegations made against us or our collaborators.

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

- We have a limited operating history in our business targeting Alzheimer’s disease and no products approved for commercial sale.
- Research and development of biopharmaceutical products is a highly uncertain undertaking and involves a substantial degree of risk and our business is heavily dependent on the successful development of our product candidates.
- We are concentrating a substantial portion of our research and development efforts on the diagnosis and treatment of Alzheimer’s disease, an area of research that has recorded many clinical failures.
- We may encounter substantial delays in our clinical trials or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.
- Our clinical trials may fail to demonstrate evidence of the safety and efficacy of our product candidates, which would prevent, delay, or limit the scope of regulatory approval and the commercialization of our product candidates.
- We may need to obtain substantial additional financing to complete the development and any commercialization of our product candidates.
- We are a small company with no sales force and may not be successful in our efforts to commercialize any product candidates which are approved.
- Our CRO, contract manufacturers and other third party vendors may fail to perform as anticipated.
- We may be unable to protect our intellectual property rights or trade secrets.
- We may be subject to third-party claims of intellectual property infringement.
- We may not succeed in our maintenance or pursuit of licensing rights or third-party intellectual property necessary for the development of our product candidates.
- Enacted or future legislation or regulatory actions may adversely affect our product pricing, or limit the reimbursement we may receive for our products.
- A significant breakdown, security breach or interruption affecting our internal computer systems, or those used by our third-party vendors and research collaborators, may compromise the confidentiality of our financial or other proprietary information, result in material disruptions of our products and operations and adversely affect our reputation.
- We may be unsuccessful at hiring and retaining qualified personnel.
- We and certain of our directors and executive officers have been named as defendants in lawsuits that could result in substantial costs and divert management’s attention.
- Recessionary fears, high interest rates, inflation or other macroeconomic or political factors beyond our control may reduce demand for office space in the Austin, Texas area and may cause the market value of our commercial real estate property to decline.
- We may fail to find new tenants to occupy office space that may become vacant and available for lease in the future.

Please also refer to the section entitled “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as such risk factors may be amended, updated or modified periodically in our reports filed with the U.S. Securities and Exchange Commission (the “SEC”) for further information on these and other risks affecting us.

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

This 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 benefited from longstanding scientific and financial support from the National Institutes of Health (“NIH”). The contents of this Quarterly Report on Form 10-Q are solely our responsibility and do not necessarily represent any official views of NIH, the Department of Health and Human Services, or the United States government.

Overview

Cassava Sciences, Inc. is a clinical-stage biotechnology company based in Austin, Texas. Our mission is to detect and treat neurodegenerative diseases, such as Alzheimer’s disease. Our novel science is based on stabilizing – but not removing – a critical protein in the brain. Our lead therapeutic drug candidate, simufilam, is being evaluated for the proposed treatment of Alzheimer’s disease dementia in Phase 3 clinical studies.

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

We currently have two biopharmaceutical assets under development:

- our lead therapeutic product candidate, called simufilam, is a novel oral treatment for Alzheimer’s disease dementia; and
- our lead investigational diagnostic product candidate, called SavaDx, is a novel way to detect the presence of Alzheimer’s disease from a small sample of blood.

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

Our lead product candidate, simufilam, is a proprietary small molecule (oral) drug. Simufilam targets an altered form of a protein called filamin A (FLNA) in the Alzheimer’s brain. Published studies have demonstrated that the altered form of FLNA causes neuronal dysfunction, neuronal degeneration and neuroinflammation. We are currently conducting a Phase 3 program with simufilam in patients with mild-to-moderate Alzheimer’s disease dementia.

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

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

Simufilam was discovered and designed in-house and was characterized by our academic collaborators during research activities that were conducted from approximately 2008 to date. SavaDx is being developed in-house with outside collaborators. We own exclusive, worldwide rights to drug and diagnostic assets and related technologies, without royalty obligations to any third party. Our patent protection with respect to simufilam and use of simufilam for Alzheimer's disease and other neurodegenerative diseases currently runs through 2039 and includes seven issued U.S. patents. In addition, we have patent protection with respect to simufilam for use in treating certain cancers that runs through 2034. Our patent estate further includes patents and patent applications for related compounds and treatments. Corresponding foreign filings have been made for each of the U.S. filings.

About Alzheimer's Disease

Alzheimer's disease is a progressive neurodegenerative disorder that affects cognition, function and behavior. As of 2021, there were approximately 55 million people worldwide living with dementia, a figure expected to increase to 139 million by 2050 according to outside sources. The annual global cost of dementia is now above \$1 trillion, according to Alzheimer's Disease International, a charitable organization.

Phase 2a Study

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

Phase 2b Study

In September 2020, we announced final results of a Phase 2b study with simufilam in Alzheimer's disease. In this clinical study funded by the NIH, Alzheimer's patients treated with 50 mg or 100 mg of simufilam twice-daily for 28 days showed statistically significant ($p < 0.05$) improvements in CSF biomarkers of disease pathology, neurodegeneration and neuroinflammation, versus Alzheimer's patients who took placebo. In addition, Alzheimer's patients treated with simufilam showed improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo. Cognitive improvements correlated most strongly with decreases in levels of P-tau181, an exploratory 'research use only' non-safety related biomarker that suggests brain changes from Alzheimer's disease. Materials labeled as Research Use Only are intended for products that are still under development and are not commercially distributed.

Open-label Study Strategy

Much of the value of our open-label study is to support simufilam's long-term safety profile in patients. We believe a well-designed, long-term, open-label study is an exercise in prudent risk-management. Clinical results serve as a tool to help inform and manage the inherent risks and uncertainties of drug development for undertaking a large, expensive Phase 3 clinical testing program.

Open-label Study Top-line Results

In March 2020, we initiated a long-term, open-label study to evaluate simufilam, our lead drug candidate, in patients with Alzheimer's disease. This study was funded in part by a research grant award from NIH. The study was designed to evaluate the long-term safety and tolerability of simufilam 100 mg twice daily for 12 or more months. Another study objective was to assess exploratory efficacy endpoints, such as changes in cognition, and biomarkers.

In January 2023, we announced positive top-line Phase 2 results for our open-label study. The study enrolled over 200 patients with mild-to-moderate Alzheimer's disease (MMSE 16-26). Endpoints were measured at baseline (study entry) and month 12.

Alzheimer's is a degenerative disease of the brain. Over time, cognition progressively worsens in the mild-to-moderate stages of Alzheimer's as the disease takes its toll. ADAS-Cog scores that change minimally (or improve) over 1 year is a highly desirable outcome in a clinical study of patients with mild-to-moderate Alzheimer's disease.

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

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

Response Analysis – baseline to month 12

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

Analysis of Efficacy Endpoints

Efficacy outcomes were analyzed by an independent, outside biostatistical consulting firm led by Suzanne Hendrix, PhD. The pre-specified primary efficacy endpoint was change in baseline on ADAS-Cog11, a cognitive scale widely used in Alzheimer’s clinical research. Exploratory endpoints included the Mini-Mental State Examination (MMSE) to assess disease stage by cognitive impairment; the Neuropsychiatric Inventory (NPI10) to assess dementia related behavior; and the Geriatric Depression Scale (GDS). The Full Analysis Set (FAS) population (N=216) was used for the statistical analysis of efficacy endpoints.

Alzheimer’s is a progressive disease. Severity of disease is typically assessed by MMSE score. In this study, mild patients are MMSE 21-26; moderate patients are MMSE 16-20. Mild and moderate sub-groups showed notable differences on changes in ADAS-Cog mean scores, baseline to month 12 (lower is better):

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

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

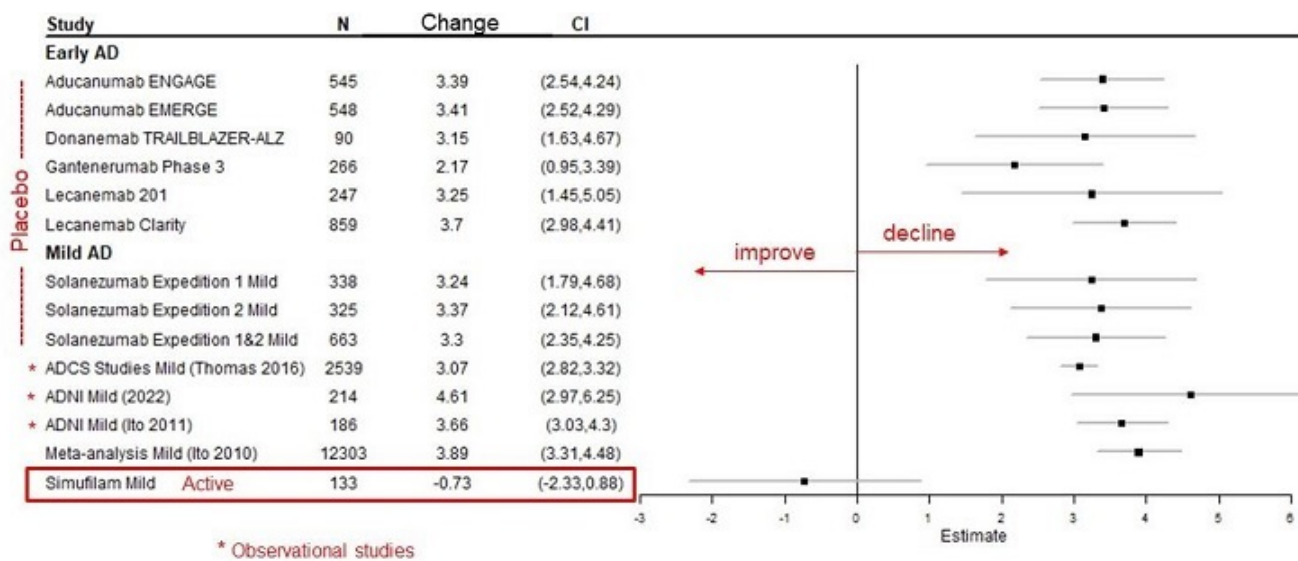


Figure 1: Statistical model of simufilam versus historical 1-year placebo declines on ADAS-Cog in early disease and mild disease.1

Safety Data

Simufilam 100 mg twice daily was generally safe and well tolerated in this open-label study. There were no drug-related serious adverse events. Three treatment-emergent adverse events (TEAEs) occurred in 7% or more of study patients: COVID-19 (12%), urinary tract infection (10%) and headache (9%). Reported TEAEs are based on all study patients who received at least one dose of drug. The top three reasons for patient discontinuations were withdrawal of informed consent (N=14), adverse events (N=13) and patient non-compliance (N=7).

Biomarker Data

Exploratory biomarkers were analyzed from cerebrospinal fluid (CSF) collected from 25 patients in the open-label study who agreed to undergo a lumbar puncture at baseline and again after 6 months of treatment. CSF samples were analyzed blind by our academic collaborator at City University of New York. All CSF biomarkers were 'research use only', non-safety-related exploratory biomarkers. We previously announced results of this bioanalysis in a press release dated July 29, 2021.

P-values shown below are baseline vs. 6-month levels by paired t-test:

- CSF biomarkers of disease pathology, t-tau and p-tau181, decreased 38% and 18%, respectively (both $p < 0.00001$)
- CSF biomarkers of neurodegeneration, neurogranin and neurofilament light chain (NfL), decreased 72% and 55%, respectively (both $p < 0.00001$)
- CSF biomarkers of neuroinflammation, sTREM2 and YKL-40, decreased 65% and 44% (both $p < 0.00001$)

Limitations of Open-label Study and Top-line Results

Data results from our open-label safety study do not constitute, and should not be interpreted as, regulatory evidence of safety or efficacy for simufilam in Alzheimer's disease. Rigorous evidence for drug safety and efficacy is derived from one or more large, randomized, placebo-controlled studies. The open-label design and size of this study may introduce clinical or statistical bias or may generate results that may not fully distinguish between drug effects and random variation. Different methods of statistical analysis on clinical data from the same study may lead to objectively different numerical results. These and other statistical and clinical features of our open-label study add complexity or limitations to the scope of data interpretation. In addition, 'top-line data' is a summary of the clinical data prior to the completion of a full and final audit or quality-control of the clinical database. We communicated top-line data so that stakeholders had timely access to a summary of the study's findings prior to us receiving the final dataset. Final data may change from initial top-line data.

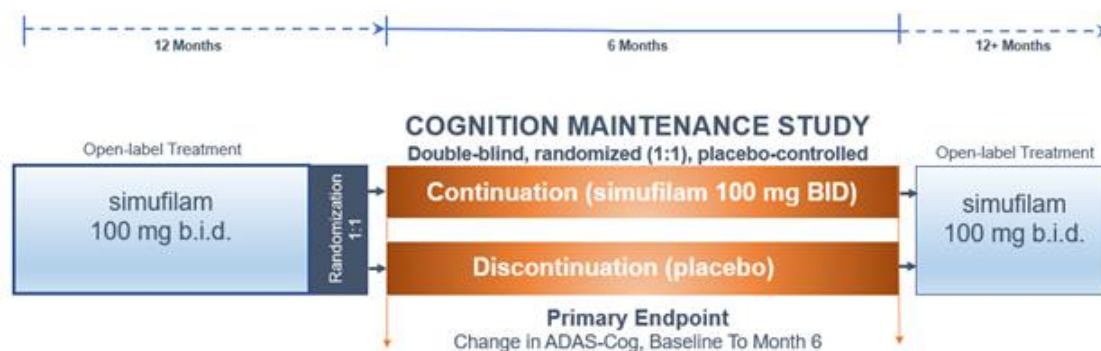
¹ Figure 1: Forest plot model by our independent consultant, Pentara Corporation. Data was sourced from non-randomized studies (i.e., ADNI) and randomized, controlled trials conducted by other sponsors in patients with early (i.e., MCI + mild) and mild Alzheimer's disease.

Cognition Maintenance Study (aka, Randomized Withdrawal Study)

In May 2021, we initiated a Cognition Maintenance Study (CMS). The CMS is a randomized, withdrawal study design. ICH² defines this type of study design as follows: “In a randomized withdrawal trial, subjects receiving a test treatment for a specified time are randomly assigned to continued treatment with the test treatment or to placebo (i.e., withdrawal of active therapy) ... Any difference that emerges between the group receiving continued treatment and the group randomized to placebo would demonstrate the effect of the active treatment.”

The CMS study design is intended to evaluate simufilam’s effects on cognition and health outcomes in Alzheimer’s patients who continue with drug treatment versus patients who discontinue drug treatment. It is a double-blind, randomized, placebo-controlled study of simufilam in patients with mild-to-moderate Alzheimer’s disease. Study patients are randomized (1:1) to simufilam or placebo for six months. To enroll in this study, patients must have previously completed 12 months or more of open-label treatment with simufilam. Final enrollment was 157 patients. See Figure 2.

Figure 2. Cognition Maintenance Study Design



Top-line Results

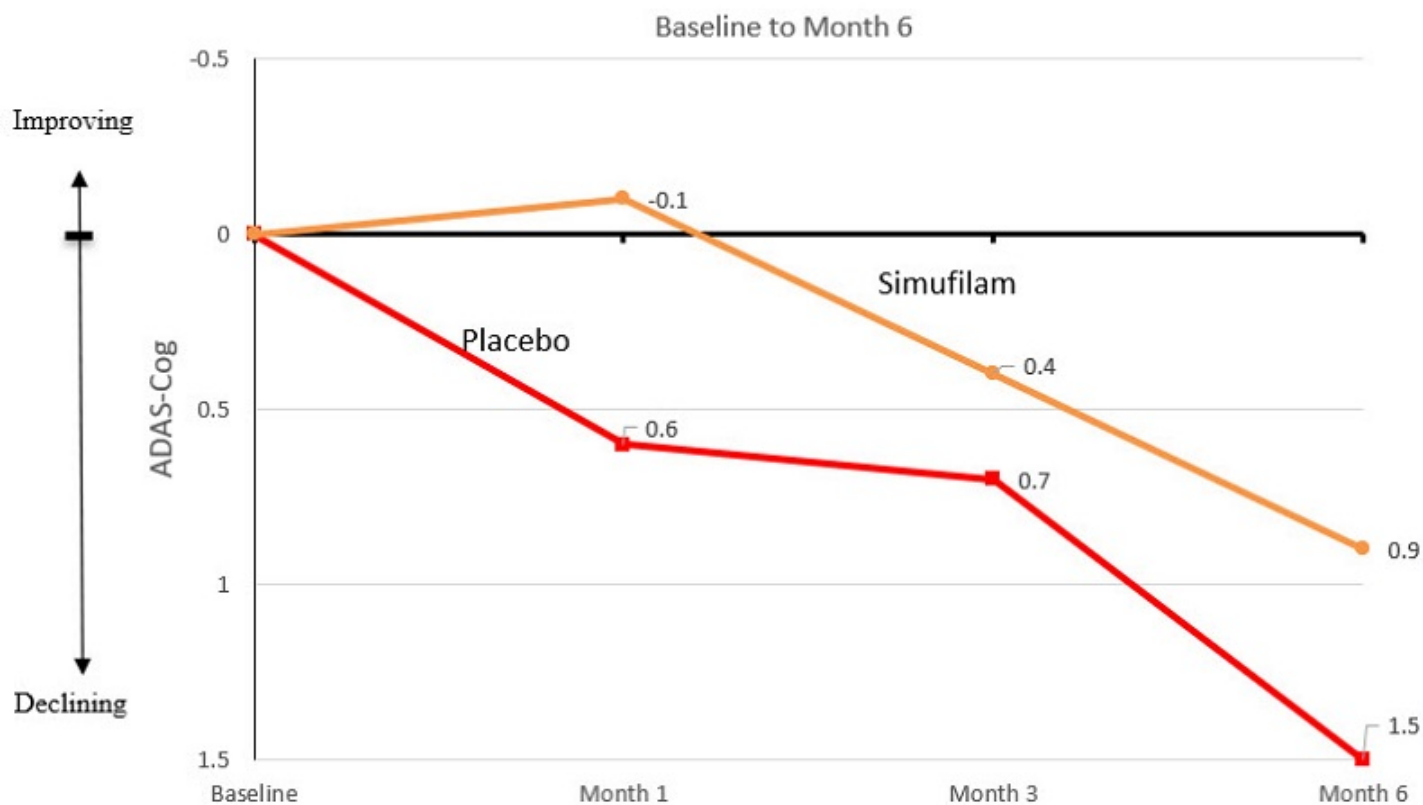
Simufilam treatment for 6 months slowed cognitive decline by 38% compared to placebo in mild-to-moderate Alzheimer’s disease (MMSE 16-26). The placebo arm declined 1.5 points on ADAS-Cog, and this arm declined at all measured timepoints. The simufilam arm declined 0.9 points on ADAS-Cog, a 38% difference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

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

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

² International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), Topic E10, Choice of Control Group in Clinical Trials.

CHART 1 - Decline in Cognition Scores, FAS



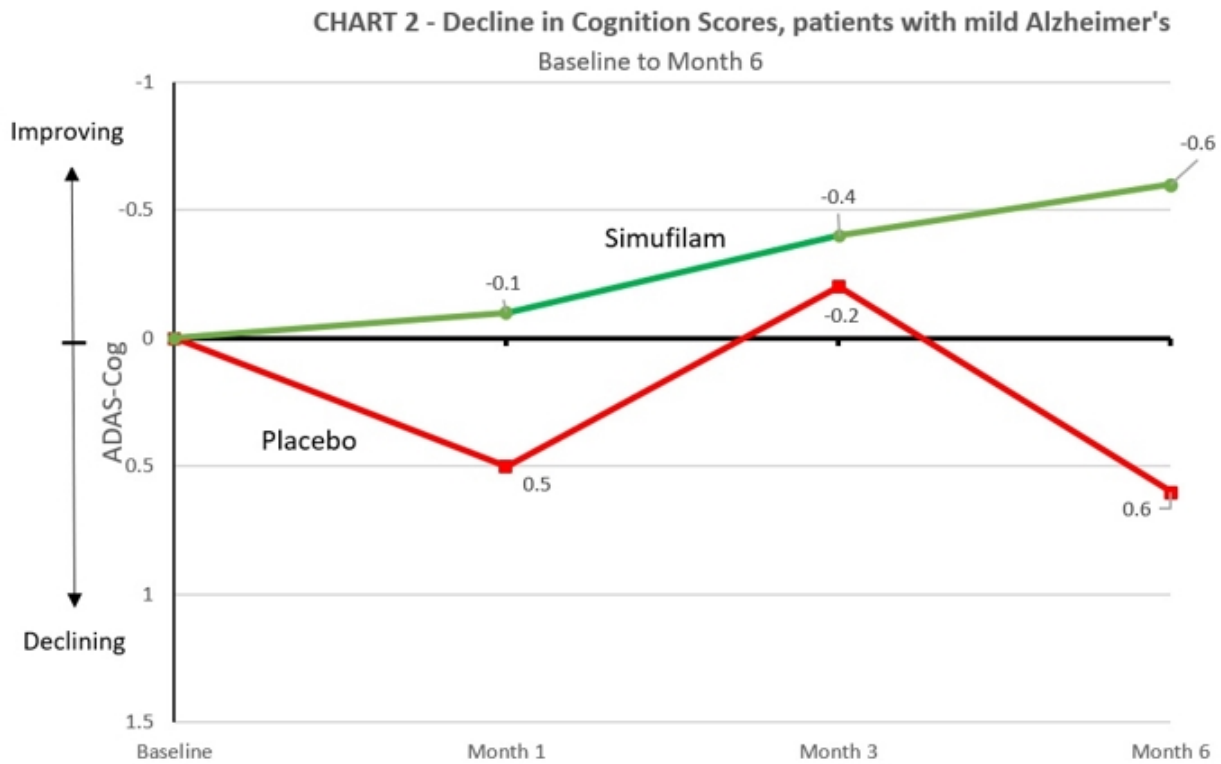
Upon randomization into the CMS, mean baseline MMSE scores were 18.6 and 18.1 for the simufilam and placebo arms, respectively. Mean baseline ADAS-Cog scores were 19.3 and 21.9 for the simufilam and placebo arms, respectively.

Simufilam Drug Effects Favored Patients with Mild Alzheimer’s Disease.

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

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

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



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

Simufilam for 18 months stabilized cognition in mild Alzheimer’s disease.

After taking open-label simufilam for 12 months, 76 patients with mild Alzheimer’s disease (MMSE 21-26) enrolled in the CMS and were randomized to receive either simufilam (N=40) or placebo (N=36) for 6 months. Mild patients randomized to simufilam in the CMS showed no material decline in ADAS-Cog scores over 18 months as a group, indicating stable cognition. Mild patients randomized to placebo in the CMS (and therefore withdrawn from simufilam treatment for 6 months) declined by 0.8 points in ADAS-Cog as a group. See Figure 3.

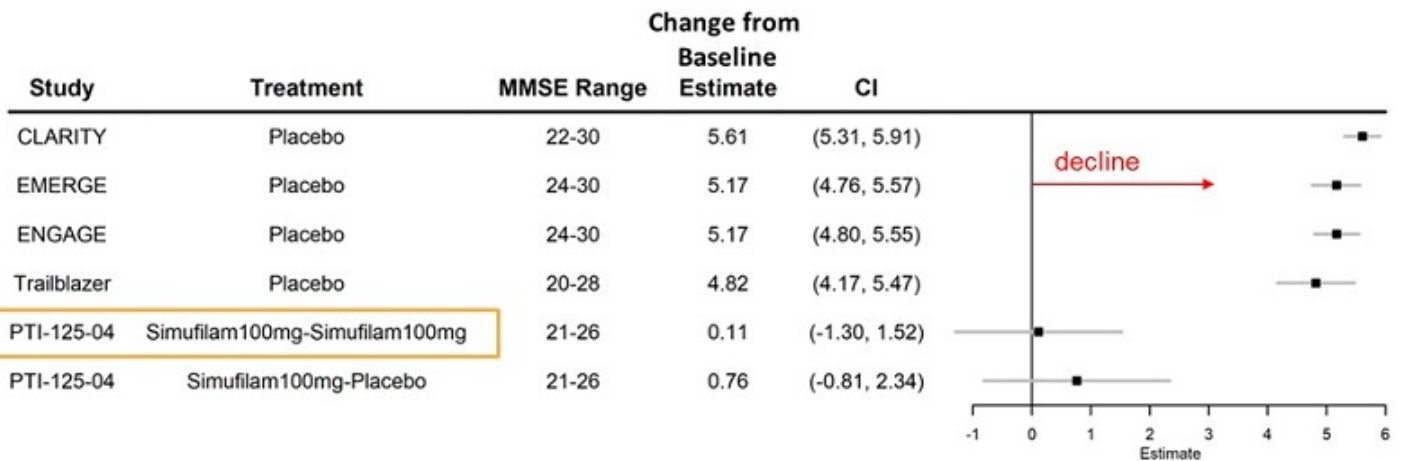


Figure 3. Historical declines on ADAS-Cog over 18 months in Alzheimer's disease (MMSE 20-30), placebo arms vs simufilam treatment.¹ Notes: results shown for CLARITY P3 trial of lecanemab; EMERGE and ENGAGE P3 studies of aducanumab; and TRAILBLAZER P3 trial of donanemab; in this figure, the CMS is referred to as the ‘PTI-125-04’ study; ‘Simufilam100mg-Simufilam100mg’ refers to patients who received simufilam in both the open-label phase and the CMS; ‘Simufilam100mg-Placebo’ refers to patients who received simufilam in the open-label phase and placebo in the CMS.

¹ Figure 3: Forest plot by our independent consultant, Pentara Corporation. Data was sourced from the placebo groups in randomized, controlled trials of monoclonal antibodies conducted by other sponsors in Alzheimer’s disease (MMSE 20-30).

Safety Data

Simufilam 100 mg twice daily was safe and well tolerated in this study. There were no drug-related serious adverse events. No treatment-emergent adverse events (TEAEs) occurred in 5% or more of study participants in the CMS, except for COVID-19 which was reported in 6% of patients on drug vs 5% of patients on placebo, and falls, which was reported in 5% of patients on placebo vs 1% of patients on drug.

Discussion

The CMS was a randomized withdrawal study. Patients who completed 12 months of open-label simufilam treatment were all invited to participate in the CMS. It is not known how long a washout period may be needed to remove lingering drug effects, if any, from prior treatment with open-label simufilam for 12 months.

In this small study of oral simufilam in patients with mild-to-moderate Alzheimer's disease, the pre-specified cognitive endpoint showed a 38% decline in ADAS-Cog over six months in favor of simufilam (not statistically significant), with good drug safety. Effects were pronounced in mild patients. Mean baseline MMSE and ADAS-Cog scores were approximately balanced given the small size of each arm.

Analysis of Efficacy Endpoints

The pre-specified cognition endpoints were analyzed by Pentara Corporation, an independent consulting firm that specializes in complex statistical analysis of clinical trial results. Suzanne Hendrix, PhD, CEO of Pentara, has over 150 peer-reviewed publications of clinical trial results and statistical approaches for clinical trials, many focusing on statistical methodology for Alzheimer's disease.

Chain of Custody for Clinical Data

Investigator sites collected clinical data from study participants. Sites entered their clinical data directly into an electronic data capture system managed by an independent, outside data management vendor. The data management vendor also maintains the clinical database. The data management vendor transmitted the clinical database directly to Pentara Corporation for analysis.

Study Limitations

The CMS is a proof-of-concept study involving a small number of patients and limited data. Top-line clinical CMS results do not constitute, and should not be interpreted as, regulatory evidence of safety or efficacy for simufilam in Alzheimer's disease. Rigorous evidence for drug safety and efficacy is derived from one or more large, randomized placebo-controlled Phase 3 studies. The limited size of the CMS may introduce clinical or statistical bias or may generate results that may not fully distinguish between drug effects and random variation. Different methods of statistical analysis on clinical data from the same study may lead to objectively different numerical results. These and other statistical and clinical features of our CMS study add complexity or limitations to the scope of data interpretation. In addition, 'Top-line data' is a summary of the clinical data prior to the completion of a full and final audit or quality-control of the clinical database. We are communicating top-line data so that stakeholders may have timely access to a summary of the CMS findings prior to us receiving the final dataset. Final data may change from initial top-line data.

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

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

In February 2021, we announced the successful completion of our EOP2 meeting. Official meeting minutes confirm that we and FDA are aligned on key elements of a Phase 3 clinical program for simufilam. FDA has agreed that the completed Phase 2 program, together with an ongoing and well-defined Phase 3 clinical program, are sufficient to show evidence of clinical efficacy for simufilam in Alzheimer’s disease. There is also agreement that the use of separate clinical scales to assess cognition (ADAS-cog¹) and function (ADCS-ADL²) are appropriate co-primary endpoints of efficacy. A clinical scale that combines cognition and function, such as iADRS³, is a secondary efficacy endpoint.

Special Protocol Assessments

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

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

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

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

Phase 3 Drug Supply

We have entered into a drug supply agreement with Evonik Industries AG for simufilam. Under the agreement, Evonik supplies and is expected to continue to supply us with large-scale, clinical-grade quantities of simufilam. Evonik is one of the world’s largest contract development and manufacturing organizations for pharmaceutical ingredients. Other vendors supply excipients, the finished dosage form (i.e., simufilam tablets), drug packaging, package labeling and other critical steps in the supply chain for Phase 3 drug supply.

Phase 3 Clinical Program Overview

Our Phase 3 program consists of two large, double-blind, randomized, placebo-controlled studies of simufilam in patients with mild-to-moderate Alzheimer’s disease dementia. Both studies are designed to measure changes in cognition and function during their treatment period. Highlights of this clinical program are summarized in Figure 4.

In June 2021, we announced the selection of Premier Research International as our CRO to help conduct our Phase 3 clinical program. Phase 3 clinical sites are located in the United States, Canada, Puerto Rico, Australia, and South Korea.

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

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

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

Figure 4. Summary of Our Phase 3 Clinical Program

	Enrollment	Simufilam Treatment	Length of Treatment	Co-Primary Endpoints		Secondary Endpoints	
				Cognition Scale	Function Scale	Cognition + Function Scale	Dementia-related Behavior Scale
ReThink-ALZ	~ 800 Patients	100 mg BID	52 weeks	ADAS-Cog12	ADCS-ADL	iADRS	NPI
ReFocus-ALZ	~ 1,100 Patients	100 mg or 50 mg BID	76 weeks	ADAS-Cog12	ADCS-ADL	iADRS	NPI

RETHINK-ALZ and REFOCUS-ALZ

In Fall 2021, we announced initiation of our two Phase 3 studies of simufilam in mild-to-moderate Alzheimer’s disease dementia. By early November 2023, we had announced the completion of patient enrollment in both Phase 3 studies. A total of approximately 1,900 patients have enrolled in these studies.

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

- ▶ Enrollment completed – approximately 800 patients with mild-to-moderate Alzheimer’s disease dementia.
- ▶ Patients are randomized (1:1) to simufilam 100 mg or placebo twice daily.
- ▶ Patients are treated for 12 months.
- ▶ The co-primary efficacy endpoints are ADAS-Cog12¹, a cognitive scale, and ADCS-ADL², a functional scale; both are standard clinical tools in trials of Alzheimer’s disease.
- ▶ A secondary efficacy endpoint is iADRS³, a standard clinical tool in trials of Alzheimer’s disease that combines cognitive and functional scores from ADAS-Cog & ADCS-ADL.
- ▶ Other secondary endpoints include plasma biomarkers of disease and NPI⁴, a clinical tool that assesses the presence and severity of dementia-related behavior.

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

- ▶ Enrollment completed – approximately 1,100 patients with mild-to-moderate Alzheimer’s disease dementia.
- ▶ Patients are randomized (1:1:1) to simufilam 100 mg, 50 mg, or placebo BID.
- ▶ Patients are treated for 76 weeks.
- ▶ The co-primary efficacy endpoints are ADAS-Cog12¹, a cognitive scale, and ADCS-ADL², a functional scale; both are widely used clinical tools in trials of Alzheimer’s disease.
- ▶ A secondary efficacy endpoint is iADRS³, a widely used clinical tool in trials of Alzheimer’s disease that combines cognitive and functional scores from ADAS-Cog & ADCS-ADL.
- ▶ Other secondary endpoints include CSF, plasma and imaging biomarkers of disease and NPI⁴, a clinical tool that assesses the presence and severity of dementia-related behavior.

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

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

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

⁴ Neuropsychiatric Inventory (NPI)

Phase 3 Entry Criteria Includes a Plasma Assay for Phosphorylated Tau (pTau)

We believe plasma levels of pTau proteins can provide independent confirmation of Alzheimer's neuropathology. RETHINK-ALZ and REFOCUS-ALZ studies use a 'research use only', non-safety related exploratory P-tau181 plasma assay to qualify mild-to-moderate Alzheimer's patients. The plasma assay we use does not rely on age, APOE-gene status or complex algorithms to provide a result.

Data and Safety Monitoring Board (DSMB)

In September 2023, we announced a positive interim safety review of simufilam in on-going Phase 3 clinical trials in patients with Alzheimer's disease. A scheduled meeting of a DSMB recommended that both of our Phase 3 studies of simufilam continue as planned, without modification. This DSMB only reviewed patient safety. It did not assess drug efficacy.

Interim MRI Safety Data

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

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

The new safety finding is based on an independent, interim neuroradiological evaluation of brain MRIs taken at week 40 in a blinded sub-study of 180 Alzheimer's patients enrolled in our on-going 76-week Phase 3 clinical trial of simufilam in mild-to-moderate Alzheimer's (NCT#05026177). Final MRI data is expected at the conclusion of this Phase 3 study.

Open-label Extension Study for the Phase 3 Program

In October 2022, we announced the initiation of an open-label extension study for our Phase 3 program. This study is designed to provide no-cost access to oral simufilam for up to one year to Alzheimer's patients who have successfully completed a Phase 3 study of simufilam and who meet other entry criteria.

The open-label extension study is expected to generate long-term safety and tolerability data for (oral) simufilam 100 mg twice daily over 52 weeks. There is no obligation for a patient or a physician to participate in the open-label extension study. Each clinical investigational site and each patient chooses whether to participate in this open-label extension study. Patient enrollment for this study began November 2022.

Publication Confirming Mechanism of Action of Simufilam

In September 2023, we announced the publication of new research that confirms the biological activity of simufilam. Researchers at the Cochin Institute (Paris, France) used a highly precise cell-based assay to show that simufilam interrupts amyloid binding to the $\alpha 7$ nicotinic acetylcholine receptor ($\alpha 7nAChR$). We believe this protein interaction underlies simufilam's mechanism of action in Alzheimer's disease. The research appears in a special issue of *International Journal of Molecular Sciences*, a peer-reviewed scientific publication.

Publication Showing Simufilam Suppresses Overactive mTOR

In June 2023, we announced the publication of new research that showed the effects of simufilam on mTOR. Scientific literature shows overactive mTOR plays a key role in aging, Alzheimer's disease and other conditions. When functioning normally, mTOR monitors cellular needs and is activated by insulin. The new published research shows mTOR is overactive in lymphocytes isolated from blood collected from Alzheimer's patients versus healthy controls. After oral administration of simufilam 100 mg twice daily to Alzheimer's patients for 28 days, lymphocytes showed normalized mTOR activity and restored mTOR sensitivity to insulin. These data suggest a meaningful impact of simufilam on mTOR signaling. The research appeared in *Frontiers in Aging*, a peer-reviewed scientific publication.

SavaDx

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

The regulatory pathway for SavaDx may eventually include formal analytical validation studies and clinical studies that support evidence of sensitivity, specificity and other variables in various healthy and diseased patient populations. We have not conducted such studies and do not expect to conduct such studies in 2023.

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

Financial Overview

We have yet to generate any revenues from product sales. We have an accumulated deficit of \$359.9 million at September 30, 2023. These losses have resulted principally from costs incurred in connection with research and development activities, salaries and other personnel-related costs and general corporate expenses. Research and development activities include costs of clinical and preclinical trials as well as clinical supplies associated with our product candidates. Salaries and other personnel-related costs include stock-based compensation associated with stock options and other equity awards granted to employees and non-employees. Our operating results may fluctuate substantially from period to period as a result of enrollment rates of clinical trials for our product candidates, timing of preclinical activities and our need for clinical supplies.

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

- continue our ongoing Phase 3 program with simufilam;
- manufacture large-scale supplies for simufilam;
- conduct other preclinical and clinical studies for our product candidates;
- seek regulatory approvals for our product candidates;
- develop, formulate, manufacture and commercialize our product candidates;
- implement additional internal systems and develop new infrastructure;
- acquire or in-license additional products or technologies, or expand the use of our technology;
- maintain, defend and expand the scope of our intellectual property;
- incur costs related to legal proceedings and claims, including U.S. government inquiries; and
- hire additional personnel.

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

We focus substantially all of our research and development efforts in the development of simufilam. Research and development expenses for our investigational diagnostic product candidate, SavaDx, represented less than 1% of total research and development expenses for the periods presented. The following table summarizes expenses by category for research and development efforts (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Clinical trials	\$ 19,532	\$ 14,778	\$ 57,018	\$ 39,592
Pre-clinical projects	1,290	1,022	4,464	2,411
Chemical, Manufacturing and Controls costs ("CMC costs")	602	668	2,834	2,080
Personnel related	1,450	1,365	4,273	4,278
Stock-based compensation	405	399	1,186	1,234
Other	324	294	917	785
	<u>\$ 23,603</u>	<u>\$ 18,526</u>	<u>\$ 70,692</u>	<u>\$ 50,380</u>

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.

During the three and nine months ended September 30, 2023, we did not receive reimbursement from NIH research grants. During the three and nine months ended September 30, 2022, we received \$0.4 million and \$0.9 million from NIH research grants, respectively. These reimbursements were recorded as a reduction to our research and development expenses.

Estimating the dates of completion of clinical development, and the costs to complete development, of our product candidates would be highly speculative, subjective and potentially misleading. Pharmaceutical product candidates take a significant amount of time to research, develop and commercialize. The clinical trial portion of the development of a new drug alone usually spans several years. 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 nine months ended September 30, 2023 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, 2022, as filed with the SEC on February 28, 2023.

Results of Operations – Three and Nine Months Ended September 30, 2023 and 2022

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 \$23.6 million and \$18.5 million during the three months ended September 30, 2023 and 2022, respectively. This 27% increase was due primarily to increasing enrollment and costs to conduct the ongoing Phase 3 clinical program and open-label studies in simufilam compared to the prior year.

Research and development expenses were \$70.7 million and \$50.4 million during the nine months ended September 30, 2023 and 2022, respectively. This 40% increase was due primarily to increasing enrollment and costs to conduct the ongoing Phase 3 clinical program and open-label studies in simufilam as well as higher preclinical costs compared to the prior year.

We expect research and development expense to continue to increase in 2023 compared to 2022 as we conduct a Phase 3 clinical program and other clinical studies with simufilam, continue to hire new personnel, manufacture drug supply, and continue our development efforts.

General and Administrative Expense

General and administrative expenses consist of personnel costs, allocated expenses and other expenses for outside professional services, including legal, human resources, audit and accounting services. Personnel costs consist of salaries, bonus, benefits and stock-based compensation. Allocated expenses consist primarily of facility costs for our Company owned office complex in Austin, Texas. Depreciation and amortization for office space leased but not occupied by the Company is included in general and administrative expense. Depreciation and amortization for office space occupied by the Company is allocated between general and administrative expense and research and development expense. We also incur expenses associated with operating as a public company, including additional legal fees, expenses related to compliance with the rules and regulations of the SEC and Nasdaq, additional insurance and audit expenses, investor relations activities, Sarbanes-Oxley compliance expenses and other administrative expenses and professional services.

General and administrative expenses were \$4.3 million and \$2.8 million during the three months ended September 30, 2023 and 2022, respectively. The 52% increase was due primarily to \$1.0 million in higher legal expenses due to ongoing legal matters as well as a \$0.5 million increase in stock-based compensation expense due to new grant awards compared to the prior year.

General and administrative expenses were \$12.5 million and \$8.7 million during the nine months ended September 30, 2023 and 2022, respectively. The 43% increase was due primarily to \$2.2 million in higher legal expenses due to ongoing legal matters, a \$1.1 million increase in stock-based compensation expense due to new grant awards as well as an increase in headcount and personnel costs compared to the prior year.

We expect general and administrative expense for 2023 will continue to increase compared to 2022 due primarily to stock-based compensation increases due to new grant awards during the period and higher legal and professional fees related to ongoing securities class action and derivative lawsuits, governmental investigations as well as the Company's lawsuit against a hedge fund and certain individuals who we believe executed a "short and distort" campaign against the Company.

Interest Income

Interest income was \$2.0 million and \$0.9 million during the three months ended September 30, 2023 and 2022, respectively.

Interest income was \$6.3 million and \$1.2 million during the nine months ended September 30, 2023 and 2022, respectively.

The increase in interest income was due to increases in interest rates compared to the prior periods.

We expect interest income to continue to increase in 2023 compared to 2022 due to increases in interest rates.

Other income, net

We record the activities related to leasing office space to third parties in buildings we own as other income, net, as leasing is not core to the Company's operations. Other income, net, was \$223,000 and \$210,000 during the three months ended September 30, 2023 and 2022, respectively. Other income, net, was \$0.6 million and \$0.7 million during the nine months ended September 30, 2023 and 2022, respectively. Other income, net, was lower in the three and nine months ended September 30, 2023 as occupancy related expenses were higher in 2023 compared to the prior year periods as the Company began occupying approximately 25% of the property beginning late August 2022.

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 September 30, 2023, cash and cash equivalents were \$142.4 million.

2022 Registered Direct Offering

On November 22, 2022, we completed a common stock offering pursuant to which certain investors purchased 1,666,667 shares of common stock at a price of \$30.00 per share. Net proceeds of the offering were approximately \$47.3 million after deducting offering expenses.

At-the-Market Common Stock Offering

On May 1, 2023, we entered into an at-the-market offering program (“ATM”) to sell, from time to time, shares of our common stock having an aggregate offering price of up to \$200 million in common stock pursuant to a shelf registration statement that was filed with the SEC on May 1, 2023 and became effective immediately upon filing. We are obligated to pay a commission of up to 3% of the gross proceeds from the sale of shares of common stock in the offering. We are not obligated to sell any shares in the offering.

There were no common stock sales under the ATM during the three and nine months ended September 30, 2023.

In March 2020, we entered into an at-the-market offering program (“2020 Program”) to sell, from time to time, shares of our common stock having an aggregate offering price of up to \$100 million in transactions pursuant to a shelf registration statement that was declared effective by the SEC on May 5, 2020. We gave notice of termination for the 2020 Program effective on April 26, 2023, which was effective May 1, 2023. There were no common stock sales under the 2020 Program through its termination.

2020 Cash Incentive Bonus Plan Obligations

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

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

The Company’s market capitalization, including all outstanding stock options, was \$89.4 million at the inception of the Plan in August 2020. If the Company were to exceed a \$5 billion market capitalization for no less than 20 consecutive trading days, and conditions noted above for payment are met, all Plan milestones would be deemed achieved, in which case total cash bonus awards would range from a minimum of \$111.4 million up to a hypothetical maximum of \$289.7 million.

The Company’s potential financial obligation to plan participants at September 30, 2023 totaled \$6.5 million (after the March 2023 Plan amendment), based upon the achievement of one Plan milestone in the Company’s market capitalization in 2020. No actual cash bonus payments have been made to any Plan participant, as the Company has not yet satisfied all the conditions necessary for amounts to be paid under the Plan. During the year ended December 31, 2021, the Company’s market capitalization increased substantially. These increases triggered the achievement of 11 additional Plan milestones. Collectively, the achievement of such milestones could trigger potential Company obligations to Plan participants ranging from a minimum of \$74.9 million up to a hypothetical maximum of \$202.3 million, with exact amounts to be determined by the Compensation Committee and contingent upon future satisfaction of a Performance Condition.

No Valuation Milestones were achieved during the 2022 or the nine months ended September 30, 2023.

No actual cash payments were authorized or made to participants under the Plan as of September 30, 2023, or through the filing date of this Form 10-Q.

Use of Cash

Net cash used in operating activities was \$59.7 million for the nine months ended September 30, 2023, resulting primarily from the net loss of \$76.3 million, partially offset by an increase in accounts payable and accrued expenses of \$5.8 million, an increase in accrued developmental expenses of \$5.1 million, a decrease in in prepaid and other current assets of \$2.4 million and stock-based compensation expense of \$2.5 million.

Net cash used in operating activities was \$56.2 million for the nine months ended September 30, 2022, resulting primarily from the net loss reported of \$57.1 million, a decrease in accounts payable of \$3.6 million and accrued compensation and benefits of \$1.7 million, partially offset by a decrease in in prepaid and other assets of \$2.8 million, an increase in accrued developmental expenses of \$1.3 million and stock-based compensation expense of \$1.5 million.

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

Net cash used in investing activities during the nine months ended September 30, 2022 was \$3.0 million related to renovations and fixtures for our corporate headquarters.

Net cash provided by financing activities during the nine months ended September 30, 2023 was \$1.4 million, from the exercise of stock options.

Net cash provided by financing activities during the nine months ended September 30, 2022 was \$0.5 million, from the exercise of stock options.

Property and Leases

We own an office complex in Austin, Texas, a portion of which serves as our corporate headquarters. This property is intended to accommodate our anticipated growth and expansion of our operations in the coming years. Maintenance, physical facilities, leasing, property management and other key responsibilities related to property ownership are outsourced to professional real-estate managers. Our office complex has approximately 90,000 square feet of rentable space. At September 30, 2023, the property was over 60% leased. We occupy approximately 25% of the property since late August 2022. Virtually all tenant leases will expire in 2024. We believe tenant leases that expire in 2024 may not be extended, renewed or re-leased beyond their expiry date, in which case we will no longer receive rental payments or reimbursement for shared expense for such office space.

We previously leased a different location with approximately 6,000 square feet of office space pursuant to an operating lease in Austin, Texas expiring in April 2024. We and the landlord consented to early terminate this lease on February 22, 2023 with no continuing obligations.

Other Commitments

We have an accumulated deficit of \$359.9 million as of September 30, 2023. We expect our cash requirements to be significant in the future. The amount and timing of our future cash requirements will depend on regulatory and market acceptance of our drug candidates, the resources we devote to researching and developing, formulating, manufacturing, commercializing and supporting our products and other corporate needs. We believe that our current cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months. We may seek additional future funding through public or private financing in the future, if such funding is available and on terms acceptable to us. However, there are no assurances that additional financing will be available on favorable terms, or at all.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Interest Rate Sensitivity

We are exposed to market risk related to changes in interest rates. We had cash and cash equivalents of \$142.4 million as of September 30, 2023, which consisted primarily of U.S. Treasury securities and money market accounts.

The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain investment vehicles with high credit quality and short-term duration, in accordance with our Board-approved investment policy. Such interest-earning instruments carry a degree of interest rate risk. However, due to the generally short-term maturities and low risk profile of our cash equivalents, an immediate 100 basis point increase or decrease in interest rates during any of the periods presented would increase or decrease our annual net loss by less than \$2 million in our condensed consolidated financial statements.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures. Our management, with the participation of our 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 September 30, 2023, 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 September 30, 2023 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

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, and 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. No information is available to indicate that it is probable that a loss has been incurred or can be reasonably estimated as of the date of the condensed consolidated financial statements and, as such, no accrual for these matters has been recorded within the condensed consolidated financial statements.

Government Investigations

On November 15, 2021, the Company disclosed that certain government agencies had asked the Company to provide corporate information and documents. These were confidential requests. The Company has been voluntarily cooperating and intends to continue to cooperate with these inquiries. No government agency has informed the Company that it has found evidence of research misconduct or wrongdoing by the Company or its officers, employees or directors. No government agency has filed any claims or charges relating to these inquiries. We cannot predict the outcome or impact of these ongoing matters, including whether a government agency may pursue an enforcement action against the Company or others.

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 us and certain named officers. The complaints rely on allegations contained in Citizen Petitions that were submitted to FDA and allege that various statements made by the defendants regarding simufilam were rendered materially false and misleading. The Citizen Petitions were all subsequently denied by FDA. These actions were filed in the U.S. District Court for the Western District of Texas. The complaints seek unspecified compensatory damages and other relief on behalf of a purported class of purchasers.

On June 30, 2022, a federal judge consolidated the four class action lawsuits into one case and appointed a lead plaintiff and a lead counsel. Lead plaintiff filed a consolidated amended complaint on August 18, 2022 on behalf of a putative class of purchasers of our securities between September 14, 2020 and July 26, 2022. On May 11, 2023, the court dismissed with prejudice plaintiffs' claims against defendant Nadav Friedmann, PhD, MD, our former Chief Medical Officer and a Company director, who is now deceased, but otherwise denied defendants' motion to dismiss. Defendants filed an answer to the consolidated amended complaint on July 3, 2023. We believe the claims are without merit and intend to defend against these lawsuits vigorously. We are unable to estimate the possible loss or range of loss, if any, associated with these lawsuits.

On November 4, 2021, a related shareholder derivative action was filed, purportedly on behalf of the Company, in the U.S. District Court for the Western District of Texas, asserting claims under the U.S. securities laws and state fiduciary duty laws against certain named officers and the members of the Company's Board. This complaint relies on 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 defendant's 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. Since November 4, 2021, four additional shareholder derivative actions were filed alleging substantially similar claims, two in the U.S. District Court for the Western District of Texas, one in Texas state court (Travis County District Court) and one in the Delaware Court of Chancery. On July 5, 2022, the three federal court actions were consolidated into a single action.

On August 19, 2022, a shareholder derivative action was filed, purportedly on behalf of the Company, in the Delaware Court of Chancery, asserting claims under state fiduciary duty laws against certain named officers and members of the Company's Board. The complaint alleges, among other things, that the individual defendants breached their fiduciary duties by approving the 2020 Cash Incentive Bonus Plan in August 2020. The complaints seek unspecified compensatory damages and other relief. On January 6, 2023, the plaintiffs filed an amended complaint. Defendants filed a partial answer to the amended complaint on March 10, 2023, and moved to partially dismiss the amended complaint on March 14, 2023. Defendants' motion to dismiss remains pending. Although the plaintiffs in this derivative case do not seek relief against the Company, the Company has certain indemnification obligations to the individual defendants.

We are unable to estimate the possible loss or range of loss, if any, associated with these lawsuits.

Item 1A. Risk Factors

There have been no material changes to our risk factors from those disclosed under "Risk Factors" in Part I, Item 1A of our 2022 Annual Report on Form 10-K. The risks and uncertainties described in our 2022 Annual Report on Form 10-K are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially adversely affect our business, financial condition or results of operations.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. *Mine Safety Disclosures*

Not applicable.

Item 5. *Other Information*

During the quarter ended September 30, 2023, 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	Capital On Demand™ Sales Agreement, dated as of May 1, 2023, between Cassava Sciences, Inc. and JonesTrading Institutional Services LLC	8-K	5/1/2023	1.1	
10.2*†	Cassava Sciences, Inc. 2020 Cash Incentive Bonus Plan (As Amended March 16, 2023).	10-Q	8/3/2023	10.2	
10.3*	Cassava Sciences Non-Employee Director Compensation Plan	10-Q	8/3/2023	10.3	
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

†Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both not material and the type of information that the Company treats as private or confidential.

* Management contract, compensatory plan or arrangement.

+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/ REMI BARBIER

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

Date: November 7, 2023

/s/ ERIC J. SCHOEN

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

Date: November 7, 2023

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

I, Remi Barbier, certify that:

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

/s/ REMI BARBIER

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

Date: November 7, 2023

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: November 7, 2023

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 September 30, 2023, 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: November 7, 2023

/s/ REMI BARBIER

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

/s/ ERIC J. SCHOEN

Eric J. Schoen,
Chief Financial Officer