# Cassava Sciences Reports Third Quarter 2023 Financial and Operating Results

Nov 07, 2023

- **Enrollment completed for Phase 3 trials evaluating oral simufilam in Alzheimer's.**
- **Over 1,900 patients randomized in on-going Phase 3 trials.**
- **Top-line results for 52-week Phase 3 trial expected approximately year-end 2024; top-line results for 76-week Phase 3 trial expected approximately mid-year 2025.**
- **MRI safety data suggests simufilam is not associated with ARIA.**
- **$142.4 Million in cash and cash equivalents at September 30, 2023.**

AUSTIN, Texas, Nov. 07, 2023 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company focused on Alzheimer's disease, today reported financial and operating results for the third quarter ended September 30, 2023.

"In the third quarter, Cassava Sciences made important progress with simufilam, our lead drug candidate," said Remi Barbier, President & CEO. "This progress exemplifies our unwavering commitment to develop a new treatment option for people with Alzheimer's."

Simufilam is Cassava Sciences' proprietary oral drug candidate. This investigational drug binds to altered filamin A protein in the brain and restores its normal shape and function. By targeting altered filamin A, simufilam may help patients with Alzheimer's achieve better health outcomes.

Cassava Sciences recently announced the completion of enrollment in a pair of on-going Phase 3 trials to evaluate the safety and efficacy of oral simufilam versus placebo in Alzheimer's disease dementia. A total of 1,929 patients were randomized in these two Phase 3 trials.

The first Phase 3 trial (NCT04994483) has a 52-week treatment period; 804 Alzheimer's patients were randomized into this study. Top-line results for the 52-week Phase 3 study are currently expected approximately year-end 2024.

The second Phase 3 trial (NCT05026177) has a 76-week treatment period; 1,125 Alzheimer's patients were randomized into this study. Top-line results for the 76-week Phase 3 study are currently expected approximately mid-year 2025.

Cassava Sciences recently presented interim safety MRI data that suggests simufilam is not associated with treatment-emergent ARIA, which are imaging abnormalities. In addition, in September 2023, a Data and Safety Monitoring Board (DSMB), recommended that the Phase 3 studies continue as planned, without modification. Finally, in September 2023, a fourth academic institution showed non-clinical data in support of the biological activity of simufilam.

**Financial Results for Third Quarter 2023**

- At September 30, 2023, cash and cash equivalents were $142.4 million, with no debt.
- Net loss was $25.7 million, or $0.61 per share. This compares to a net loss of $20.3 million, or $0.51 per share, for the same period in 2022. Net loss increased due primarily to increases in patient enrollment and associated costs to conduct the Phase 3 clinical program, as well as other studies with simufilam.
- Net cash used in operations was $59.7 million during the first nine months of 2023.
- Net cash use in operations for second half 2023 is expected to be $40 to $50 million, consistent with previous guidance and driven primarily by expenses for our clinical program in Alzheimer's disease.
- Research and development (R&D) expenses were $23.6 million. This compared to $18.5 million for the same period in 2022. R&D expenses increased due primarily to increasing patient enrollment and costs to conduct the Phase 3 clinical program, as well as other studies with simufilam.
- General and administrative (G&A) expenses were $4.3 million. This compared to $2.8 million for the same period in 2022. G&A expenses increased due to activities and expenses related to legal services as well as increases in stock-based compensation.

**About Cassava Sciences, Inc.**
Cassava Sciences 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 product candidates have

not been approved by any regulatory authority, and their safety, efficacy or other desirable attributes have not been established.

For more information, please visit: https://www.CassavaSciences.com

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***Cautionary Note Regarding Forward-Looking Statements:***
*This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, that may include but are not limited to: the design, scope, conduct, continuation, completion, intended purpose, or future results of our on-going Phase 3 program of simufilam in patients with Alzheimer's disease; the suitability of clinical data from our Phase 3 program to support the filing of an NDA; any findings or recommendations by the DSMB relating to the interim safety of simufilam in our on-going Phase 3 clinical trials; interim MRI safety data for the Phase 3 program, including ARIA; the risk of current or future findings of treatment-emergent ARIA in our clinical program of simufilam; any expected clinical results of Phase 3 studies; the treatment of people with Alzheimer's disease dementia; the safety or efficacy of simufilam in people with Alzheimer's disease dementia; expected cash use in future periods; comments made by our employees regarding simufilam, drug effect, and the treatment of Alzheimer's disease; and potential benefits, if any, of our product candidates . These statements may be identified by words such as "may," "anticipate," "believe," "could," "expect," "forecast," "intend," "plan," "possible," "potential," and other words and terms of similar meaning.*

*Simufilam is our investigational product candidate. It is not approved by any regulatory authority in any jurisdiction and its safety, efficacy or other desirable attributes have not been established in patients.*

*Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Clinical results and analyses of our previous studies should not be relied upon as predictive of Phase 3 studies or any other study. Our clinical results from earlier-stage clinical trials may not be indicative of full results or results from later-stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or any scientific data we present or publish.*

*Such statements are based largely on our current expectations and projections about future events. Such statements speak only as of the date of this news release and are subject to a number of risks, uncertainties and assumptions, including, but not limited to, those risks relating to the ability to conduct or complete clinical studies on expected timelines, to demonstrate the specificity, safety, efficacy or potential health benefits of our product candidates, any unanticipated impacts of inflation on our business operations, and including those described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, and future reports to be filed with the SEC. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from expectations in any forward-looking statement. In light of these risks, uncertainties and assumptions, the forward-looking statements and events discussed in this news release are inherently uncertain and may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Except as required by law, we disclaim any intention or responsibility for updating or revising any forward-looking statements contained in this news release. For further information regarding these and other risks related to our business, investors should consult our filings with the SEC, which are available on the SEC's website at www.sec.gov.*

– Financial Tables Follow –

CASSAVA SCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited, in thousands, except per share amounts)

| | Three months ended September 30, | | Nine months ended 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) |
| Weighted-average shares used in computing net loss per share, basic and diluted | 42,002 | 40,050 | 41,845 | 40,009 |

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited, in thousands)

| | September 30, 2023 | December 31, 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 |
| Property and equipment, net | 22,077 | 22,864 |
| Operating lease right-of-use assets | — | 122 |
| Intangible assets, net | 268 | 622 |
| Total assets | $ 172,529 | $ 234,834 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities | | |
| Accounts payable | $ 9,492 | $ 4,017 |
| Accrued development expense | 7,344 | 2,280 |
| Accrued compensation and benefits | 187 | 170 |
| Operating lease liabilities, current | — | 104 |
| Other accrued 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 |
| Stockholders' equity | | |
| Common Stock and additional paid-in-capital | 514,965 | 511,091 |
| Accumulated deficit | (359,850) | (283,552) |
| Total stockholders' equity | 155,115 | 227,539 |
| Total liabilities and stockholders' equity | $ 172,529 | $ 234,834 |

Source: Cassava Sciences, Inc.