Cassava Sciences Resolves SEC Investigation

Sep 26, 2024

AUSTIN, Texas, Sept. 26, 2024 (GLOBE NEWSWIRE) -- Cassava Sciences, Inc. (“Cassava” or the “Company”) (Nasdaq: SAVA), a biotechnology company focused on Alzheimer’s disease, today announced that it has reached a settlement with the U.S. Securities and Exchange Commission (“SEC”) of negligence-based disclosure charges that resolve a previously-disclosed SEC investigation into statements made by the Company pertaining to the results of its 2020 Phase 2b clinical trial of simufilam and related matters. Two former senior employees of the Company also settled negligence-based disclosure charges brought by the SEC.

Cassava, without admitting or denying the SEC’s allegations, agreed to pay a monetary penalty of $40 million. The Company cooperated fully with the SEC’s investigation and has implemented remedial measures.

In connection with the previously-disclosed investigation by the Department of Justice (“DOJ”), the Company does not currently anticipate that DOJ’s Criminal Division will bring charges against or seek a resolution with the Company.

On July 17, 2024, Cassava announced the appointment of Richard (Rick) Barry as Executive Chairman of the Board as well as a series of actions designed to enhance corporate governance, transparency, and accountability, consistent with the Company’s commitment to the highest ethical business practices. Mr. Barry became Chief Executive Officer of Cassava on September 6, 2024.

“We would like to thank the staff of the Division of Enforcement for its professionalism and its engagement with the Company, which enabled the Board to conduct its own internal investigation and to take decisive action,” said Mr. Barry.

“Cassava is pleased to put this matter behind us,” Mr. Barry said. “We can now focus all of our attention on completion of the ongoing Phase 3 trials of simufilam. While no one can accurately predict the future, we remain hopeful that the trials will be successful and that, after a rigorous FDA review, simufilam could become available to help those suffering from Alzheimer’s disease.”

As previously announced, Cassava’s net cash use in operations for the second half of 2024 is expected to be $80 to $90 million, which includes the $40 million monetary penalty related to this resolution. The Company maintains its estimate that cash at year-end 2024 will be in a range of $117 to $127 million.

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 statements regarding: the impact on the Company of its settlement with the SEC; the status of, and developments related to, DOJ inquiries and investigations; the implementation of remedial measures and actions to enhance governance, transparency and accountability; the advancement and outcome of our on-going Phase 3 clinical trials of simufilam in patients with Alzheimer's disease; the safety or efficacy of simufilam in people with Alzheimer’s disease dementia; potential benefits, if any, of our product candidates; and expected cash balances and cash use in future periods. These statements may be identified by words such as “anticipate,” “believe,” “could,” “expect,” “forecast,” “intend,” “may,” “plan,” “possible,” “potential,” “will,” and other words and terms of similar meaning.

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, risks relating to: any continuing investigation by DOJ, including investigation of the conduct alleged in the indictment of Dr. Hoau-Yan Wang announced by DOJ on June 28, 2024; approval by the U.S. District Court of the settlement with the SEC; the ability to conduct or complete clinical studies on expected timelines and within expected budgets; the ability to demonstrate the specificity, safety, efficacy, or potential health benefits of our product candidates; our current expectations regarding timing of clinical data for our Phase 3 clinical trials; any expected clinical results of Phase 3 clinical trials; potential benefits, if any, of our product candidates; and those described in the section entitled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023, in our Quarterly Report on Form 10-Q for the period ended June 30, 2024, and in subsequent reports 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.

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

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