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Reviva Pharmaceuticals Holdings, Inc. (RVPH: NASDAQ)

RVPH: Shareholder Letter Introduces New IP

Research Note

Letter to Shareholders

On behalf of Reviva Pharmaceuticals Holdings, Inc. (NASDAQ: RVPH), Chief Executive Officer, Dr. Laxminarayan Bhat, composed a letter to shareholders acknowledging the difficult path over the last year. The missive justified the capital raises over the last 10 months, citing the priorities of strengthening the balance sheet, supporting operations to achieve the next milestone and developing brilaroxazine to address schizophrenia and potentially other neuropsychiatric indications. The letter illuminates the pathway ahead for the RECOVER 2 trial and introduces new intellectual property related to brilaroxazine's formulation that may extend its patent life.

The most recent capital raise generated $10 million in gross proceeds bringing cash on the balance sheet to $23 million following the transaction. The amount provides sufficient funds to support the initiation of the RECOVER 2 trial in 2Q:26, enroll first trial patients in 3Q:26 and support further trial and operational costs until 1Q:27.

The news that can most significantly impact brilaroxazine's valuation is the new composition of matter patent that Reviva has filed. If granted by the United States Patent and Trademark Office (USPTO) and if the FDA agrees to the proposed development strategy, it will reset brilaroxazine's patent clock. The patent was filed earlier this year, which would provide protection for brilaroxazine that will expire in 2046. Not only would this provide brilaroxazine with additional patent protection for the schizophrenia indication, but it would also have implications for other indications in bipolar disorder, major depressive disorder and Reviva's other pipeline targets that would use the same formulation.

While the exact modification has not been disclosed, management indicates that the new formulation will use Generally Recognized as Safe (GRAS) substances that are expected to enhance the properties of the Active Pharmaceutical Ingredient (API). Salt and polymorph changes are the most common modifications and are allowed by the FDA but must be approved. These changes can change and improve solubility, bioavailability and stability among other features. Salt changes require new supporting Chemistry, Manufacturing and Controls (CMC) and pharmacokinetic (PK) data prior to approval. If a drug has already received marketing approval, a Prior Approval Supplement (PAS) or New Drug Application (NDA) is required, which requires substantially more time, effort and cost to execute. Polymorph changes need a CMC update and potentially bridging studies if bioavailability is affected. The FDA allows changes to a drug's formulation but requires supportive data that is part of the development and registration process. If there is a change in the formulation between trials, the agency requires data showing that the new formulation is bioequivalent or that the change does not negatively impact the product's profile.

If the changes to the formulation are allowed by the FDA, then Reviva could see a dramatic extension of intellectual property (IP) protection. The formulation of brilaroxazine used in the RECOVER trial was supported by a composition of matter patent that expires in November 2030. The new filed patent could extend this to 2046. Before all of this can be integrated in our model, the new patent must be reviewed and granted and the FDA must allow the change.

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We expect to see a busy next few months at Reviva that will be occupied by trial preparation activities, interactions with the FDA to permit the new formulation of brilaroxazine and first enrollment in RECOVER 2. The trial is expected to run for about a year and the program will require additional capital mid-way through. The trial should wrap up and provide a topline readout before year end 2027. This sets up Reviva for an NDA submission in early 2028 for FDA review.

Milestones

- FDA agreement on trial protocol for RECOVER 2 – 2025
- Publication of clinical vocal biomarker data in Biological Psychiatry – January 2026
- New brilaroxazine patent submitted to USPTO for new formulation – 1Q:26
- Initiate RECOVER 2 Phase III trial (site selection) – 2Q:26
- FDA consent on use of new brilaroxazine formulation in RECOVER 2 – mid-year 2026
- Enroll first patient in RECOVER 2 Phase III trial – 3Q:26
- Completion of RECOVER 2 trial enrollment – 3Q:27
- Topline readout of RECOVER 2 Phase III trial – 2H:27
- Potential brilaroxazine NDA submission to FDA for schizophrenia – 1H:28

Summary

One of the primary concerns for investors has been the limited patent life left on the original formulation of brilaroxazine, which was set to expire in 2030. Applying an approach used by others, Reviva is changing the formulation of brilaroxazine in order to enhance the drug's properties and reset the IP clock. If successful, brilaroxazine's patent protection may be extended to 2046. This new formulation would also be used for other brilaroxazine indications such as major depressive disorder (MDD) and bipolar disorder. In his investor letter, CEO Bhat also reiterated several of the milestones announced earlier this year with respect to starting the RECOVER 2 trial and enrolling the first patients in 3Q:26. The trial should take about a year to complete allowing for topline readout before year end 2027 and an NDA submission in 2028.

There is a bright side to the delay which is a potential NDA submission which includes a new formulation of brilaroxazine that could substantially extend patent protection. If the company had moved more quickly and received approval for the previous formulation, it would have opened the door for generic competition sooner.

While it has been a difficult path, the data for brilaroxazine has demonstrated better safety and efficacy compared with other atypical antipsychotics. Its performance has impressed us with an attractive biomarker profile that aligns with improving schizophrenia symptoms. We see a best-in-class safety and efficacy profile for brilaroxazine which has been demonstrated in a Phase II and Phase III study. While it has been frustrating that capital providers have not recognized brilaroxazine's potential to the same extent that we do, Reviva now has a chance to generate more supportive data and move closer to its NDA submission date.

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