UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2024
or
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from ____ to ____
Commission file number: 001-38634

Reviva Pharmaceuticals Holdings, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**85-4306526**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
10080 N. Wolfe Road, Suite SW3-200 **Cupertino, CA**	**95014**
(Address of principal executive offices)	(Zip Code)

(408) 501-8881
(Registrant's 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, par value $0.0001 per share	RVPH	The Nasdaq Capital Market
Warrants to purchase one share of Common Stock	RVPHW	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of a share of the registrant's common stock on June 28, 2024 as reported by the Nasdaq Capital Market on such date, was approximately $31.8 million. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 14, 2025 the number of outstanding shares of the registrant's common stock, par value $0.0001 per share, was 46,739,949.

DOCUMENTS INCORPORATED BY REFERENCE

None.

REVIVA PHARMACEUTICALS HOLDINGS, INC.
TABLE OF CONTENTS

This page intentionally left blank

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this report on Form 10-K may include, for example, statements about:

- the success of our current or planned clinical trials through all phases of clinical development, including our ability to conduct and complete clinical trials in accordance with projected timelines, our ability to achieve the desired results, and our ability to successfully complete requisite regulatory review and approval processes;
- our ability to obtain the necessary financing to continue to conduct our business operations as planned, and to conduct our ongoing and planned trials, and continue and complete the planned development and commercialization of our product candidates;
- our ability to grow and manage growth economically;
- our ability to retain key executives and medical and science personnel;
- the possibility that our products in development succeed in or fail clinical trials or are not approved by the U.S. Food and Drug Administration or other applicable authorities;
- the possibility that we could be forced to delay, reduce or eliminate our planned clinical trials or development programs;
- our ability to obtain approval from regulatory agents in different jurisdictions for our current or future product candidates;
- changes in applicable laws or regulations;
- changes to our relationships within the pharmaceutical ecosystem;
- the performance of third-party suppliers and manufacturers and our ability to find additional suppliers and manufacturers and obtain alternative sources of raw materials;
- our current and future capital requirements to support our development and commercialization efforts and our ability to satisfy our capital needs;
- our ability to access capital on acceptable terms in a rising interest rate and tighter credit environment;
- expectations regarding our ability to continue as a going concern;

- the accuracy of our estimates regarding expenses and capital requirements, including estimated costs of our clinical studies;
- our limited operating history;
- our history of operating losses in each year since inception and expectation that we will continue to incur operating losses for the foreseeable future;
- the valuation of our private common warrants could increase the volatility in our net income (loss);
- changes in the markets that we target;
- our ability to maintain or protect the validity of our patents and other intellectual property;
- our exposure to any liability, protracted and costly litigation or reputational damage relating to data security;
- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;
- any disruption to our business that may occur on a longer-term basis should we be unable to remediate the material weaknesses we have identified in our internal controls;
- our ability to maintain the listing of our common stock and listed warrants on Nasdaq; and
- the possibility that we may be adversely affected by other economic, business, and/or competitive factors.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in such forward-looking statements. Please see "Part I-Item 1A-Risk Factors" for additional risks which could adversely impact our business and financial performance.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaims any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

Part I

Item 1. BUSINESS

All references in this report to "Reviva," the "Company," "we," "us," or "our" mean Reviva Pharmaceuticals Holdings, Inc. and its subsidiaries unless we state otherwise, or the context otherwise indicates.

Company Overview

We are a late-stage pharmaceutical company that discovers, develops, and seeks to commercialize next-generation therapeutics for diseases representing significant unmet medical needs and burdens to society, patients, and their families. Our current pipeline focuses on the central nervous system, inflammatory, and cardiometabolic diseases. We use a chemical genomics driven technology platform and proprietary chemistry to develop new medicines. Our pipeline currently has two drug candidates, brilaroxazine (RP5063) and RP1208. Both are new chemical entities discovered in-house. We have been granted composition of matter patents for both brilaroxazine and RP1208 in the United States (U.S.), Europe, and several other countries.

Our lead drug candidate, brilaroxazine, is in clinical development and is intended to treat multiple neuropsychiatric indications. These include schizophrenia, bipolar disorder ("BD"), major depressive disorder ("MDD"), attention–deficit/hyperactivity disorder ("ADHD"), behavioral and psychotic symptoms of dementia and Alzheimer's disease ("BPSD"), and Parkinson's disease psychosis ("PDP"). Furthermore, brilaroxazine is also ready for clinical development for two respiratory indications — pulmonary arterial hypertension ("PAH") and idiopathic pulmonary fibrosis ("IPF"). The U.S. Food and Drug Administration ("FDA") granted Orphan Drug Designation to brilaroxazine for the treatment of PAH in November 2016 and IPF in April 2018. Brilaroxazine also is in preclinical development for the treatment of psoriasis.

Our primary focus is to complete the clinical development of brilaroxazine for the treatment of acute and maintenance schizophrenia.

On October 30, 2023, we announced positive topline results from our Phase 3 RECOVER 1 trial (the "RECOVER-1 Trial"), which is a global Phase 3, randomized, double-blind, placebo-controlled, multicenter study designed to assess the safety and efficacy of brilaroxazine in approximately 400 patients with acute schizophrenia compared to placebo. See "Phase 3 RECOVER-1 Data" below for more details on brilaroxazine development.

Subject to the receipt of additional financing, we may also continue the clinical development of brilaroxazine for the treatment of BD, MDD, ADHD, BPSD, PDP, PAH and IPF. Moreover, subject to the receipt of additional financing, we may also advance the development of our second drug candidate, RP1208, for the treatment of depression and obesity.

Phase 3 RECOVER-1 Data

On October 30, 2023, we announced positive topline results and successful completion of our pivotal RECOVER-1 Trial evaluating the efficacy, safety and tolerability of once-daily brilaroxazine, a serotonin dopamine signaling modulator in adults with schizophrenia. The trial successfully met its primary endpoint at the 50 mg dose, with brilaroxazine at that dose achieving a statistically significant and clinically meaningful 10.1-point reduction in Positive and Negative Syndrome Scale (PANSS) total score compared to placebo (-23.9 brilaroxazine 50 mg vs. -13.8 placebo, $p<0.001$) at week 4. Brilaroxazine also achieved statistically significant and clinically meaningful reductions in all major symptom domains and secondary endpoints at week 4 with the 50 mg dose vs. placebo. The 15 mg dose of brilaroxazine was numerically superior to placebo on the primary endpoint and most secondary endpoints, and reached statistical significance on two key secondary endpoints.

Key statistically significant and clinically meaningful improvements with brilaroxazine vs. placebo in patients with schizophrenia and a mean PANSS total score of 97-99 at baseline include:

Figure	Primary and Secondary Endpoints	Point Reduction/ Improvement for Brilaroxazine 50 mg vs. Placebo at Week 4	Cohen's d Effect Size	P Value
Figure 9	PANSS Total Score	10.1	*0.6*	*< 0.001*
Figure 10A	Positive Symptoms	2.8	*0.5*	*< 0.001*
Figure 10B	PANSS Excitement/Agitation	2.1	*0.5*	*< 0.001*
Figure 11A	Negative Symptoms (NS)	2.0	*0.4*	*0.003*
Figure 11B	NS Marder Factor	2.1	*0.4*	*0.002*
Figure 12A	PANSS Social Cognition	1.6	*0.5*	*< 0.001*
Figure 12B	Personal & Social Performance	6.3	*0.5*	*< 0.001*
Figure 13B	CGI-S Score	≥1	*0.5*	*< 0.001*

Key clinical safety and tolerability findings of brilaroxazine support a well-tolerated safety profile

- No drug related serious adverse events (SAEs) or treatment-emergent SAEs (TESAEs) observed or major safety concerns reported for brilaroxazine after 4 weeks of treatment;
- No incidence of suicidal ideation;
- No significant change in bodyweight and blood glucose levels compared to placebo;
- Significant decrease in cholesterol, LDL and increase in HDL compared to placebo;
- Significant decrease in prolactin and no change in thyroid levels compared to placebo;
- Akathisia and extrapyramidal symptoms <1% reported for brilaroxazine 50 mg and none for 15 mg;
- Common brilaroxazine treatment-emergent adverse events (TEAEs) were headache (<6%) and somnolence (≤7.5%) generally transient in nature; and
- Low discontinuation rates with brilaroxazine that were less than placebo (16% in brilaroxazine 50mg and 19% in brilaroxazine 15mg vs. 22% placebo).

The clinical development plan for brilaroxazine also includes the completed positive Phase 2 REFRESH trial, an ongoing 1-year open label extension (OLE) trial evaluating long-term safety and tolerability, and a soon to be initiated registrational global, randomized 4-week Phase 3 RECOVER 2 trial (the "RECOVER-2 Trial"). We reported positive preliminary topline data from the OLE in December 2024, with the OLE expected to complete in Q2-2025, and we expect to initiate the registrational RECOVER-2 Trial in mid-2025, subject to receipt of additional financing, with topline readout anticipated in the third quarter of 2026. RECOVER-2 was originally designed as a 6-week study, but after discussion between Reviva and FDA, the agency has agreed that it can be conducted as a 4-week study. Data from these brilaroxazine clinical trials will potentially support the planned NDA submission to the FDA in the fourth quarter of 2026.

Open Label Extension (OLE) Trial- Enrollment Update and Topline Data

The OLE portion of the RECOVER Study is being conducted globally at multiple centers to assess the safety, and efficacy of brilaroxazine at flexible doses of 15, 30 or 50 mg, administered once daily for 52-weeks (1-year) in patients with stable schizophrenia. The OLE included both rollover participants from the double-blind portion of RECOVER study and de novo participants with stable schizophrenia. Long-term safety data from a minimum of 100 patients who have completed 1-year of treatment is a requirement for brilaroxazine's NDA submission to the FDA.

In November 2024, we provided an enrollment update on our ongoing OLE evaluating the long-term safety and tolerability of brilaroxazine in patients with schizophrenia, including the following:

- Global trial progressing well;
- 108 patients have completed 1-year (12-month) of treatment;
- Over 250 patients have completed 6-months of treatment;
- Blood and digital biomarkers designed to independently support efficacy; and
- Long-term safety data from 100 patients who have completed 12 months of treatment is a requirement for brilaroxazine's NDA submission to the FDA.

On December 16, 2024, we announced positive preliminary topline data from our OLE evaluating the long-term safety and tolerability of brilaroxazine in patients with schizophrenia. Administration of brilaroxazine once daily led to robust broad-spectrum efficacy that was sustained over 1 year. Brilaroxazine was generally well tolerated with no single side effect >5% and favorable compliance, with a discontinuation rate of 35% in the OLE part of this study. All three doses of brilaroxazine (15 mg, 30 mg and 50 mg) tested were efficacious and generally well-tolerated.

Key safety, efficacy and compliance findings for pooled analysis of brilaroxazine at 15, 30, and 50 mg include:

- A total number of 435 patients were enrolled in the OLE across three dose groups: 139 in brilaroxazine 15 mg, 155 in brilaroxazine 30mg and 141 in brilaroxazine 50mg
- 156 (35.86%) rollover participants from the double-blind portion of the Phase 3 trial, while 279 (64.13%) de novo participants enrolled in the OLE
- Preliminary efficacy results are presented for 113 patients who completed 52 weeks (1 year) of treatment; preliminary safety results are presented for all 435 patients who enrolled in the OLE, including patients that are still participating in the trial

Brilaroxazine across doses improved major symptom domains of schizophrenia after 1-year of treatment:

- Dose dependent efficacy at the 15, 30, and 50 mg doses was observed, with decreases in PANSS total scores of -15.2, -18.6 and -20.8 points, respectively, from baseline to end-of-treatment at 52 -week (1-year)
- Pooled data of brilaroxazine at the 15, 30, and 50 mg doses (N = 113) demonstrated clinically meaningful and sustained long-term (1-year) efficacy for schizophrenia with a significant decrease in PANSS total scores, PANSS positive symptoms, and PANSS negative symptoms compared to baseline
  - PANSS Total scores: 18.6-point decrease (71.6 → 53), $p \leq 0.0001$
  - PANSS Positive Symptoms: 5.2-point decrease (17.7 → 12.5), $p \leq 0.0001$
  - PANSS Negative Symptoms: 4.5-point decrease (19.5 → 15.0), $p \leq 0.0001$
- Brilaroxazine demonstrated strong sustained efficacy from acute through maintenance treatment over 1 -year with a decrease in PANSS Total score in rollover patients from the double-blind portion of the trial
  - ≥30-point decrease of PANSS total in 86.76% of patients
  - ≥40-point decrease of PANSS total in 64.70% of patients
  - ≥50-point decrease of PANSS total in 33.82% of patients

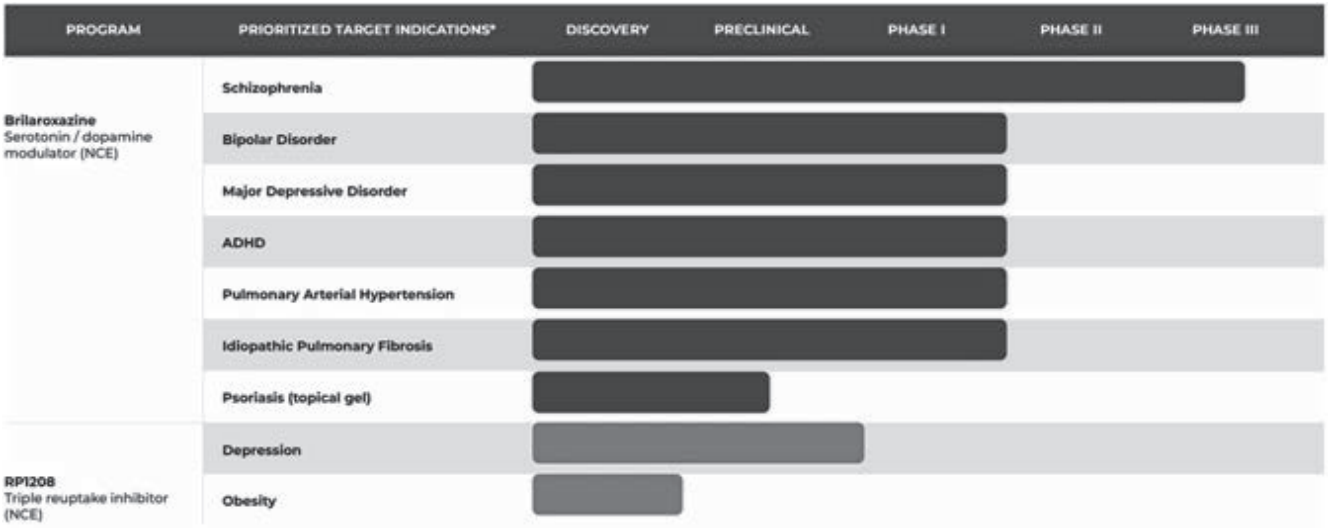
Long-term clinical safety, tolerability and adherence findings of brilaroxazine administered for up to one year support a well-tolerated safety profile:

- 15.2% of participants reported at least one treatment-related adverse event (TRAE), which were mostly mild (12.2%) or moderate (3%) in severity and transient in nature
- Most common TRAEs ≥1% were weight increase (3.2%), insomnia (1.8%) and somnolence (1.6%)
- Brilaroxazine was not associated with any clinically meaningful changes in movement disorder scales over 1 -year treatment
- No drug-related serious adverse events (SAEs) observed or major safety concerns reported for brilaroxazine after up to 1 -year of treatment; 3 serious adverse events were reported and none were related to brilaroxazine treatment
- Treatment discontinuation rate of 35% reported in this OLE, primarily due to withdrawal of consent (22%), participant lost to follow up (7%), and treatment-related adverse events (1.6%)

Collectively, the findings from the OLE (52-week/1-year) portion of the Phase 3 RECOVER study further strengthen the safety, efficacy and treatment adherence findings from the double-blind (4-week) portion of RECOVER.

Development Status Chart

The development status of the Reviva product pipeline is presented below:



Business Combination and Domestication

On December 14, 2020, our predecessor company, formerly known as Tenzing Acquisition Corp., a British Virgin Islands exempted company ("Tenzing"), and Reviva Pharmaceuticals, Inc., a Delaware corporation (together with its consolidated subsidiaries, "Old Reviva"), consummated the transactions (the "Business Combination") contemplated by the Agreement and Plan of Merger, dated as of July 20, 2020 (as amended, the "Merger Agreement"), by and among Tenzing, Tenzing Merger Subsidiary Inc., a Delaware corporation and wholly-owned subsidiary of Tenzing ("Merger Sub"), Old Reviva, and the other parties thereto. Pursuant to the Merger Agreement, Merger Sub merged with and into Old Reviva, with Old Reviva surviving as our wholly owned subsidiary. We refer to this transaction as the Business Combination. In connection with and one day prior to the completion of the Business Combination, Tenzing re-domiciled out of the British Virgin Islands and continued as a company incorporated in the State of Delaware, and changed its name to Reviva Pharmaceuticals Holdings, Inc. Prior to the completion of the Business Combination, the Company was a shell company. Following the Business Combination, the business of Old Reviva is the business of the Company.

Old Reviva was incorporated in the state of Delaware on May 1, 2006 and its subsidiary, Reviva Pharmaceuticals India Pvt. Ltd., was incorporated on December 23, 2014. Tenzing was formed pursuant to the laws of the British Virgin Islands on March 20, 2018.

About Brilaroxazine (RP5063)

Our drug candidate brilaroxazine is a novel, multimodal serotonin (5HT), dopamine (DA), and nicotinic receptor modulator. Our compound displays a high affinity for 5HT2A/2B/7 and DA2/3/4 receptors and a moderate affinity for nicotinic (nACh-α4β2) receptors (Rajagopal et al., 2017). The binding affinity of brilaroxazine to dopamine and serotonin sub-receptors in radioligand binding assays is the following (Ki, nM): dopamine D2S (0.28), D2L (0.45), D3 (3.7), and D4.4 (6.0); Serotonin 5HT1A (1.5), 5-HT2A (2.5), 5-HT2B (0.19), 5-HT2C (39), 5-HT6 (51), and 5-HT7 (2.7). Brilaroxazine displayed moderate binding affinity to nicotine- nAChR, α4β2 (Ki = 36.3 nM).

Radioactive and non-radioactive studies in rat and dog show that the gastrointestinal tract completely absorbs orally administered brilaroxazine -related material, with acceptable bioavailability in rat (22%) and dog (85%) animal models. Exposure to brilaroxazine increased in a dose-dependent manner. Once absorbed, brilaroxazine rapidly and extensively distributes into various tissues. Noteworthy is the brain with a brain:plasma ratio of ~3.5, despite high plasma protein binding (>99%) characteristics. Rat and dog hepatocytes rapidly metabolize brilaroxazine; however, human hepatocytes metabolize this compound more slowly. This finding suggests that brilaroxazine will show a low clearance in humans. We believe the risk of brilaroxazine inducing or inhibiting cytochrome P450 (CYP) at anticipated pharmacologically relevant concentrations in humans is low. Hepatic metabolism via the cytochrome P450s is the primary route of elimination with CYP3A4/5 undertaking most of the metabolism (69%), a small contribution from CYP2D6 (17%) and minor contributions by other cytochromes including extra-hepatic CYP2J2. Two metabolites in human plasma and urine display no pharmacological activity. We believe there is a low risk of inhibition and induction of human cytochromes by brilaroxazine at expected plasma concentrations clinically.

A full battery of regulatory compliant toxicology and safety pharmacology studies is complete. We believe the results from these tests support the chronic administration of brilaroxazine in clinical trials. We believe the completed safety, pharmacology and toxicology studies support several significant safety findings. These include (1) brilaroxazine is neither genotoxic nor clastogenic, (2) it does not affect the function of cardiovascular (QT interval or blood pressure) or respiratory systems, and (3) it is not phototoxic in the 3T3 *in vitro* assay.

DEVELOPMENT OF BRILAROXAZINE (RP5063) FOR NEUROPSYCHIATRIC DISEASES

Brilaroxazine Development for Schizophrenia

Schizophrenia is a complex, chronic, and debilitating psychiatric syndrome. As presented in 2020, the Schizophrenia and Related Disorders Alliance of America ("SARDAA") estimates schizophrenia can be found in approximately 1.1% of the world's population, regardless of racial, ethnic, or economic background, with approximately 3.5 million people diagnosed in the U.S. It is a complex disease involving a mix of positive and negative symptoms, along with mood disorder and cognitive impairment. While the pathology of schizophrenia is not yet fully understood, scientists implicate the dysregulation or disruption of both dopaminergic and serotonergic functions in the development of this condition. The dysregulation of serotonergic function in the brain also contributes to schizoaffective disorders, such as bipolar, major depression, and mania. Thus, the optimal treatment for schizophrenia may not rely solely on dopamine blockade. Hypothetically, it may also include the stabilization of both the dopaminergic and serotonergic systems in the brain.

Current pharmacologic treatment involves antipsychotic therapy. There are two types of antipsychotics, typical and atypical agents. Tolerability issues (e.g., neuroleptic side effects with typical agents; metabolic and cardiovascular problems with atypical medications) limit compliance and the effectiveness of both classes of medications. Hence, compliance is poor. We estimate, pursuant to a review of multiple peer reviewed articles published between 1998 and 2015, discontinuation rates of 30 – 50% in the short-term management of acute patients and 42 – 74% in the long-term treatment. Also, both classes of antipsychotics fail to provide a broad spectrum of efficacy across the major symptoms or comorbidities of schizophrenia. Thus, we believe the optimal treatment of schizophrenia requires new compounds with broader efficacy, and better safety, tolerability and compliance profiles.

We believe the majority of the FDA approved antipsychotics in the last two decades block dopamine (D) and serotonin (5HT) receptors, particularly D2 and 5HT2A receptors. Brilaroxazine possesses a potent binding and functional activity for both D2 and 5HT2A receptors. We believe these targets are critical for treating schizophrenia. In addition, brilaroxazine has potent activities for D4, 5HT1A, 5HT2B and 5HT7 receptors implicated as targets for conditions associated with schizophrenia such as negative symptoms, mood symptoms (e.g., depression, anxiety) and cognitive impairment. Brilaroxazine also exerts a moderate activity on nicotinic (nAChR, α4β2) receptor, implicated as a target for comorbid conditions in schizophrenia, depression and cognitive impairment.

Preclinical studies define the activity, pharmacokinetic, and safety profiles of brilaroxazine in animals. Rodent models of pharmacologic-induced behaviors associated with schizophrenia have demonstrated that brilaroxazine attenuates both psychosis and cognitive symptoms.

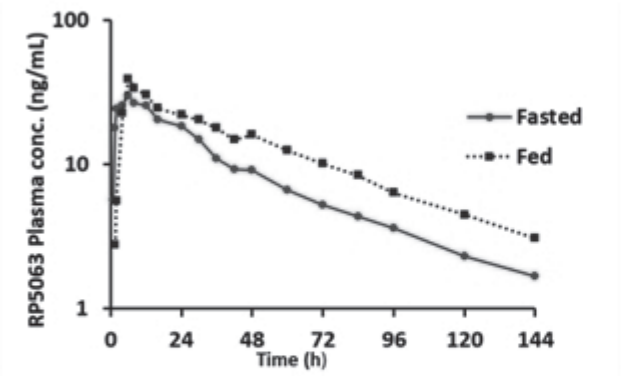
We have completed a clinical Phase 1a study in healthy subjects, a Phase 1b study in stable schizophrenia patients, a Phase 2 study in acute schizophrenia and schizoaffective patients, and the Phase 3 RECOVER-1 Trial in acute schizophrenia patients. Additionally, we announced preliminary topline data from our OLE evaluating the long-term safety and tolerability of brilaroxazine in patients with schizophrenia.

Brilaroxazine (RP5063) Phase 1 Clinical Study in Stable Schizophrenia

Phase 1a and 1b studies have defined the initial clinical experience with brilaroxazine. The first-in-human study Phase 1a involved a single-dose ascending study of 24 individuals. Initially, it examined patient cohorts receiving individual doses of 10 and 15 mg fasting; this was followed by a food-effect investigation (food versus fasting, crossover), with a 15 mg dose (Figure 1a). The multiple-dose Phase 1b study examined doses of 10, 20, 50, and 100 mg given with food over ten days in 32 randomized patients (Figure 1b). Collectively, these studies characterized the initial safety and pharmacokinetic profiles in normal healthy volunteers (Caucasian or Japanese men, 20 – 45 years) and stable patients with schizophrenia (18 – 65 years, chronic, all types with Total Positive and Negative Syndrome Scale (PANSS) score < 90 points). Brilaroxazine displayed a dose-dependent Cmax at 4 to 6 h, linear dose proportionality for both Cmax and AUC, and a half-life between 40 and 71 h. In the single-dose study, food slightly increased the extent of drug absorption. In the multiple-dose study, drug concentrations approached steady-state after 120 h (5 days) of daily dosing. Pooled data in the single-dose study indicate that the pharmacokinetic profile appeared to be comparable between Caucasians and Japanese. Study data have suggested a straightforward pharmacokinetic profile for brilaroxazine that we believe supports once-daily dosing as an orally administered agent for Phase 2 and Phase 3 evaluation.

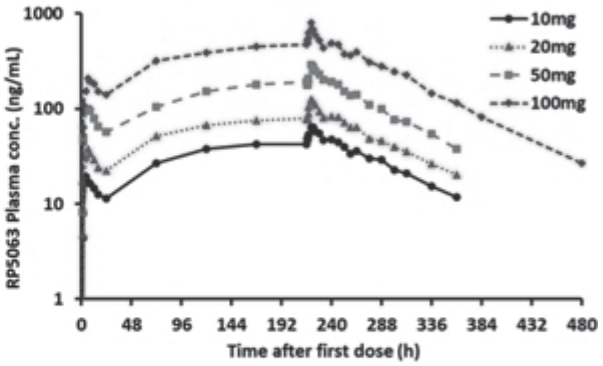
Figure 1. Brilaroxazine Phase 1 Clinical Studies, Pharmacokinetics in Healthy Subjects and Stable Schizophrenia Patients

A. Single-dose pharmacokinetics profile of brilaroxazine (15 mg) in healthy subjects



- Dose dependent and proportional increase in C_{max} and AUC_{∞}
- Half-life (T1/2 = 42 h) suitable for once a day dosing
- No significant food effect, brilaroxazine can be administered with or without food.

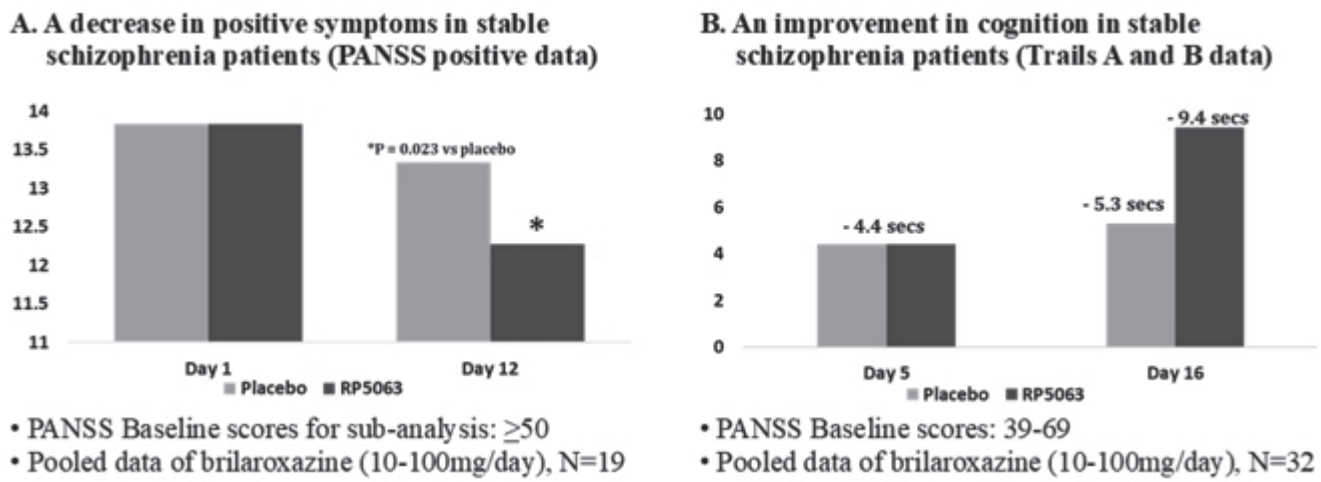
B. Multiple-dose pharmacokinetics profile of brilaroxazine (10, 20, 50 or 100 mg/day) in stable schizophrenia patients for 10 days



- Linear, predictable PK across all doses and time
- Relatively long half-life (~60 hrs); good for patient compliance, if dose missed
- Steady state in 5 days (120 hrs)
- Well tolerated, no dose limiting safety signals in ECG, clinical lab, vital signs, and physical exams

As the multiple-dose study included patients with stable schizophrenia, the data from this study provided an early assessment of the pharmacodynamics behavior and activity of brilaroxazine in this population. Notable were the results of secondary analyses to explore Positive and Negative Syndrome Scale ("PANSS") observations relevant to the effect of brilaroxazine on positive symptoms, and Trails A and B tests to assess the effect on cognition, respectively. Pooled analysis of patients with PANSS scores ≥50 at baseline showed a statistically significant reduction in positive symptoms subscale scores (Figure 2a). Furthermore, study analysis identified favorable trends in reducing PANSS total scores from baseline and in the General Psychopathology Score from baseline vs. placebo. Similarly, a pooled analysis of Trails A and B scores from baseline to day 16 showed favorable trends in the improvement of cognition in the brilaroxazine treatment groups vs. placebo.

Figure 2. Brilaroxazine Efficacy in the Phase 1B Clinical Study in Stable Schizophrenia Patients



The Phase 1b study in stable schizophrenia patients found that brilaroxazine appears to be generally well-tolerated at doses ranging from 10 – 100 mg administered once daily over ten days. Most adverse events were mild and occurred at the higher doses 50mg and 100 mg. Notable was the lack of clinically significant changes in glucose or prolactin levels, lipid profiles, and weight or ECG findings. A pharmacodynamic analysis of the multiple-dose Phase 1b study data provided early insight regarding the clinical activity of brilaroxazine relevant to psychosis, along with mood and cognitive comorbidities, in patients with stable schizophrenia. Although we believe the Phase 1b study safety and efficacy findings are encouraging, it is important to recognize its power limitations due to the relatively small sample size.

Brilaroxazine (RP5063) Phase 2 Clinical Study in Acute Schizophrenia

The Phase 2 clinical study involved patients with acute exacerbations of schizophrenia or schizoaffective disorder and was designed to evaluate the efficacy, safety, tolerability, and pharmacokinetics of brilaroxazine versus placebo. The study was a double-blind, randomized, placebo-controlled 4-week trial. Aripiprazole was included in the study purely for assay sensitivity analysis and not as a comparator. A total of 234 eligible subjects were randomized into one of five treatment groups (15, 30, 50mg brilaroxazine, aripiprazole 15mg, or placebo; 3:3:3:1:2, respectively). Recruitment of male and female subjects occurred at 22 sites in the US, India, Philippines, Malaysia, and Moldova.

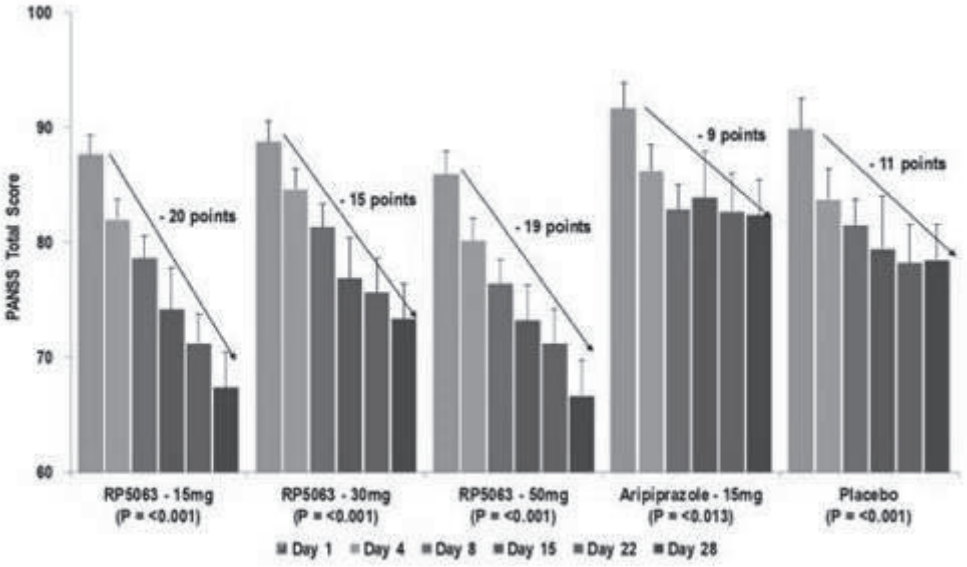
The sample size was calculated based on expected differences between the target dose of brilaroxazine and placebo of 8.3 points (standard deviation of 11.3 points, effect size = 0.735) in the primary efficacy analysis (mean change from baseline in PANSS Total Score). This plan projected a sample size of 180 completing subjects (i.e., 45 subjects in each brilaroxazine dose group; this cohort included 15 subjects in the aripiprazole group and 30 subjects in the placebo group) to achieve at least 85% power at an alpha level of 0.05% (two-sided). This level employed a t-test statistic for unequal group sizes, without controlling the alpha error in the pair-wise comparisons of the treatment groups with placebo. The statistical plan did not power the aripiprazole arm for statistical comparisons with other arms, as evaluation of this compound only assessed the study sensitivity; the study randomized 234 subjects to ensure that 180 would complete.

We conducted this study in compliance with the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Consolidated Guidelines. The FDA reviewed the protocol, as did investigational review boards/independent ethics committees, and all participating subjects provided informed consent.

The primary efficacy endpoint was the change from baseline to Day 28 or End of Treatment (EOT) on PANSS Total Score. The secondary efficacy endpoints were the change from baseline to Day 4, Day 8, Day 15, Day 22 and Day 28 on the following items: PANSS Total, PANSS Positive, and Negative subscales; 20% improvement in PANSS Total Score; Improvement by at least 1 point on the Clinical Global Impression (CGI-S); cognition by trail-making Tests A and B and the Digit Symbol Substitution Test (DSST). Safety variables included adverse events (AE), physical examinations, vital signs, body weight, laboratory measurements (hematology, serum chemistry including prolactin, urinalysis, and pregnancy tests), and electrocardiograms (ECGs). The measurement of extrapyramidal symptoms (EPS) utilized the Simpson Angus Scale (SAS), Abnormal Involuntary Movement Scale (AIMS), and the Barnes Akathisia Rating Scale (BARS). The Columbia-Suicide Severity Rating Scale (C-SSRS) assessed and classified reported suicidal behavior and depression by the Calgary Depression Scale for Schizophrenia (CDSS). Investigators collected blood samples throughout the dosing period and for 220 h beyond using a sparse sampling routine. Analysis of these samples defined the population pharmacokinetics (PK) and correlated pharmacokinetic and pharmacodynamic (PK/PD) effects.

Brilaroxazine demonstrated a sustained decrease in the total PANSS scores from Day 1 to 28 with statistically significant improvement within the group for all doses of brilaroxazine (p=<0.001) and aripiprazole (p=0.013) (Figure 3).

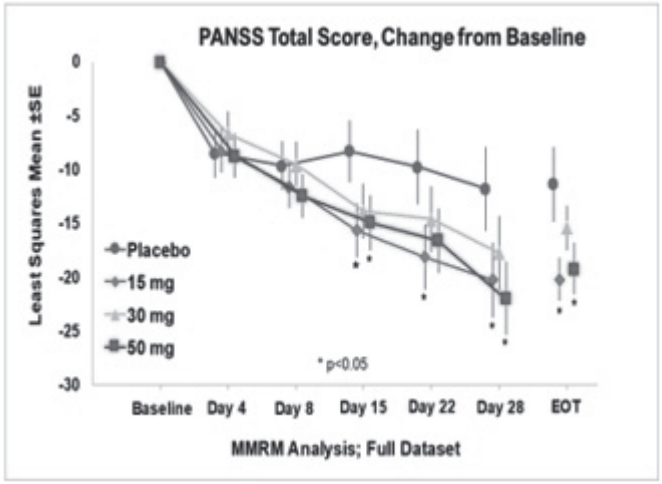
Figure 3. Brilaroxazine Efficacy in the Phase 2 Clinical Study in Acute Schizophrenia patients, Total PANSS Scores, ITT Population (4 weeks, N = 234)



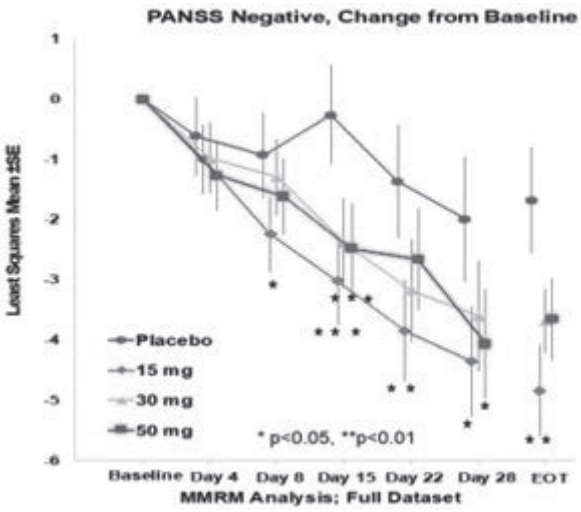
For the primary efficacy endpoint, the change in PANSS Total Score from baseline to Day 28/EOT there was a statistically significant treatment difference from placebo for the brilaroxazine 15-mg and 50-mg arms (p = 0.0212 and p = 0.0167), with a statistically significant difference versus placebo seen as early as the Day 15 assessment (mixed-effect model with repeated measures (MMRM) analyses). The 30-mg arm did not reach statistical significance (p=0.2733), although it was numerically superior. Investigators attributed the lack of significance of the brilaroxazine 30 mg dose to larger than normal early discontinuations (within 2-7 days) for reasons that were not related to the medication. Aripiprazole only showed efficacy in PANSS negative scores. PANSS subscales scores showed greater brilaroxazine improvement versus placebo in the PANSS Negative and Prosocial symptoms than the Positive symptoms (Figure 4). Both the brilaroxazine 15-mg and 50-mg treatment groups displayed statistical significance from placebo as early as Day 15 for the PANSS Negative and Prosocial scales. The 50-mg treatment group showed statistical significance at Day 28 for PANSS Positive. All brilaroxazine groups were numerically superior to placebo.

Figure 4. Brilaroxazine Phase 2 Clinical Efficacy for Acute Schizophrenia and Major Comorbid Symptoms

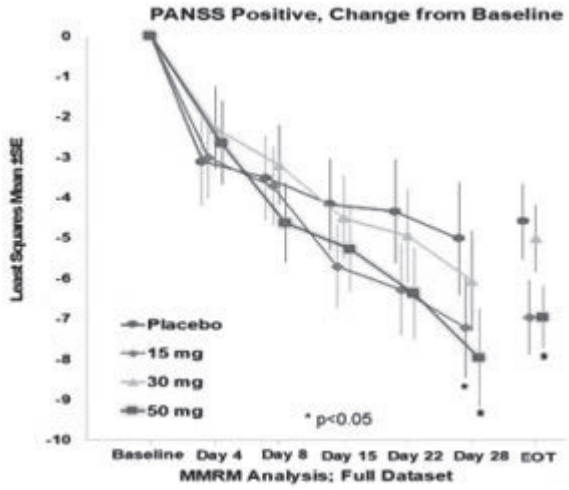
A. Efficacy Data for Acute Schizophrenia (Primary Endpoint)



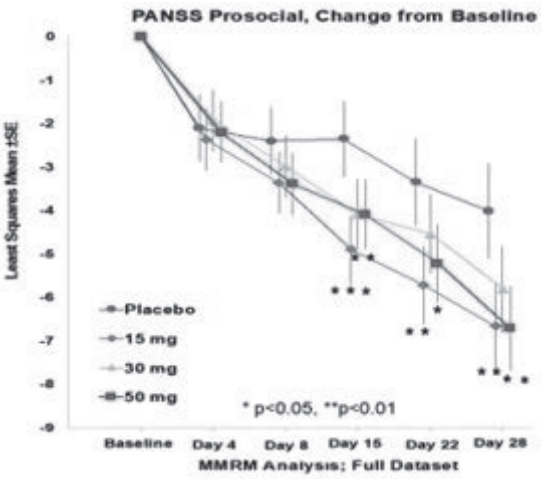
B. Efficacy Data for Negative Symptoms (Secondary Endpoint)



C. Efficacy Data for Positive Symptoms (Secondary Endpoint)

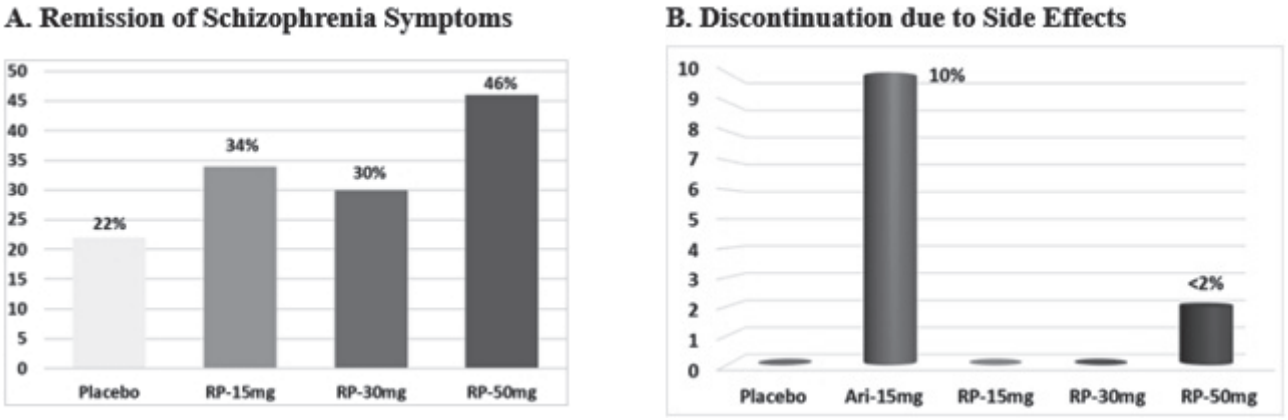


D. Efficacy Data for Social Functioning (Secondary Endpoint)



At Day 28/EOT, the frequency of a 30% improvement in total PANSS from baseline to EOT was 41%, 26%, and 39% for the respective brilaroxazine groups, versus 22% for the placebo cohort. Brilaroxazine subjects improved ≥2 points on the CGI-S by Day 28/EOT at twice the frequency of those on placebo. Brilaroxazine 15-mg, 30-mg, and 50-mg groups resulted in 46%, 37%, and 40% improvements, respectively, versus placebo showing a 19% change. Further, relative to >1 point changes, the 15-mg, 30-mg, and 50-mg brilaroxazine groups produced 73%, 58%, and 72% improvements, respectively, in the CGI-S, as compared to placebo showing 57% change. The CGI-S changes from baseline to Day 28/EOT were statistically superior to placebo for brilaroxazine 15 mg and 50 mg, while the change for 30 mg was numerically superior. Overall, brilaroxazine (15, 30, and 50mg) treated patients showed between 30-46% remission of acute schizophrenia symptoms, as compared with 22% in the placebo group (Figure 5a). As expected in a short study in patients with acute schizophrenia, there were no statistically significant differences in change from baseline for cognition scores. However, there were numerical improvements in brilaroxazine groups in the DSST, Trails A and Trails B scores for cognitive functions.

Figure 5. Brilaroxazine Phase 2 Study, Remission of Acute Schizophrenia and Discontinuation due to Side Effects



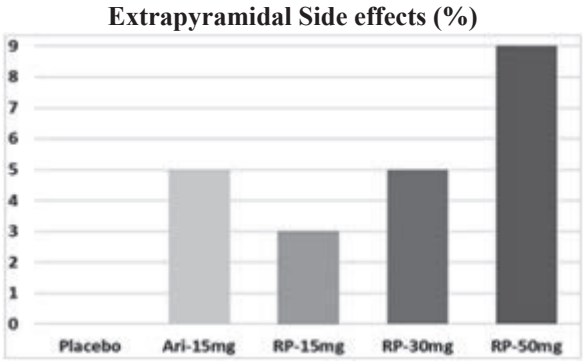
Patients tolerated doses of brilaroxazine up to 50 mg with no side effect related discontinuations in the 15 mg and 30 mg dose groups. Only <2% of patients discontinued the treatment in the 50 mg dose group compared to 10% of patients in the aripiprazole 15 mg group (Figure 5b). Treatment discontinuations for any reason with 15 mg, 30 mg, and 50 mg doses of brilaroxazine; the 15 mg dose of aripiprazole; and placebo were 14%, 25%, 12%, 35%, and 26%, respectively. Investigators attribute the higher discontinuation rate in the 30 mg group of brilaroxazine to a larger than the normal number of early discontinued patients (~10%) due to non-treatment reasons. Such early discontinuation is not uncommon in a clinical study of acute schizophrenia. The discontinuation rates with aripiprazole (35% for any reason, and 10% due to side effects) are consistent with findings in published clinical studies. Common treatment-emergent adverse events (TEAEs) were EPS (3%, 5%, and 9%) and akathisia (2%, 5%, and 10%), and as expected there seemed to be a dose-dependent increase in TEAEs in the 15, 30, and 50 mg brilaroxazine treatment groups, respectively (Figure 6).

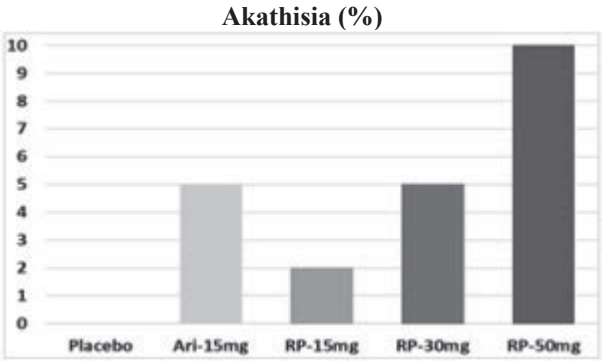
There were no clinically relevant changes from baseline in weight or body mass index (BMI); no subject had weight gain reported as a TEAE. This observation represented a clinically relevant finding because weight gain has been a common side effect of second-generation antipsychotics and identified as a key risk factor associated with increased morbidity and mortality in patients with schizophrenia with a major impact on compliance.

There were no clinically meaningful trends in laboratory parameters (including glucose, cholesterol, triglycerides or thyroid hormone T4), ECG, or vital signs. The study observed small mean decreases from baseline in prolactin levels in all treatment groups at Day 28. In addition, there were no reports of sexual side effects and no increase in suicidal ideation compared to placebo (Figure 6).

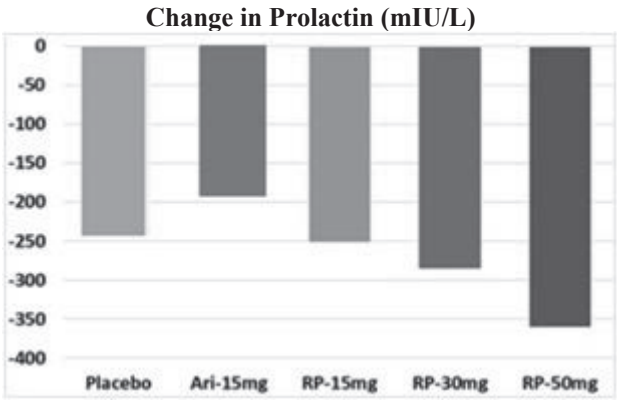
Figure 6. Brilaroxazine Side Effect Profile in the Phase 2 Clinical Study in Acute Schizophrenia (4 weeks, N=234)

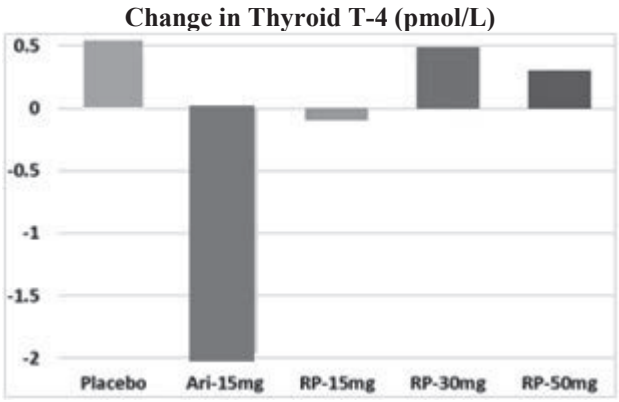
6A. CNS or Neuroleptic Side effects



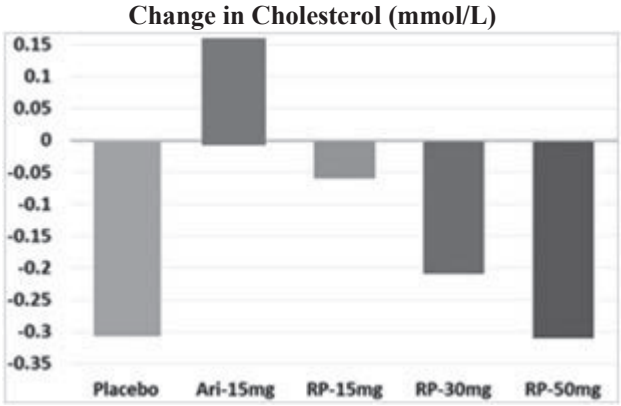


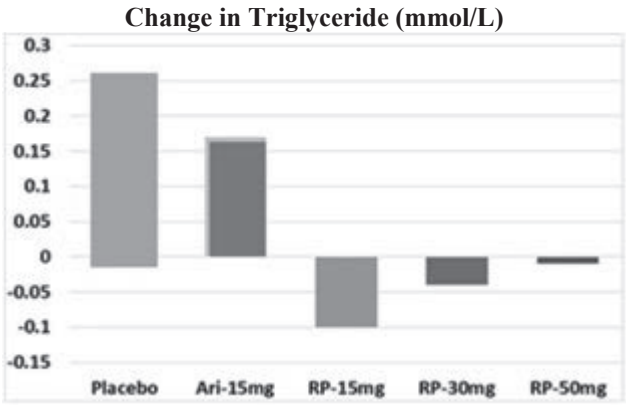
6B. Endocrine Side Effects



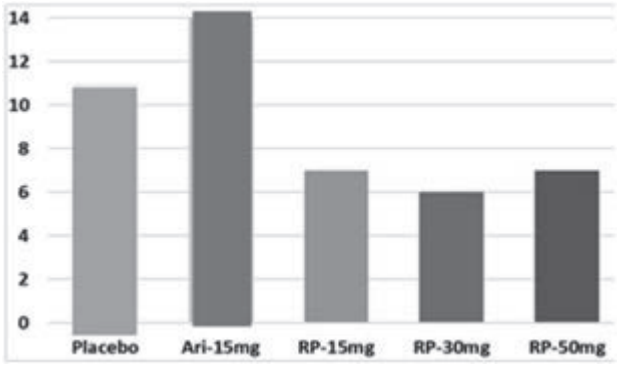


6C. Metabolic Side Effects

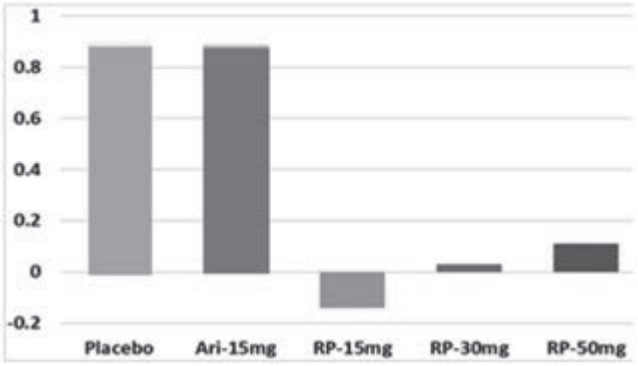




Change in Bodyweight (%)



Change in Blood Sugar (mmol/L)



Overall, all 3 fixed doses of brilaroxazine were well tolerated with no clinically relevant major adverse effects in any of the 3 brilaroxazine dosing cohorts. Particularly, there were no significant changes in: EPS (all scales of gait, akathisia, abnormal movements); metabolic parameters (body weight, blood glucose); or cardiac parameters (ECG or incidence of orthostatic hypotension). Patients with pre-existing movement disorders (e.g. EPS, akathisia) were not excluded per protocol, and most patients who reported motor side effects were on concomitant medication (e.g., anticholinergic agents) used for treating movement disorders. Since brilaroxazine is not intended as a treatment for movement disorders, patients with pre-existing movement disorders may exhibit recurrence. Therefore, it is difficult to determine the causality of motor side effects in patients with pre-existing movement disorders. There was a favorable decrease in cholesterol and triglycerides, which, along with the aforementioned lack of significant changes in weight and glucose, suggests that neither metabolic syndrome nor a prediabetic condition are caused by brilaroxazine.

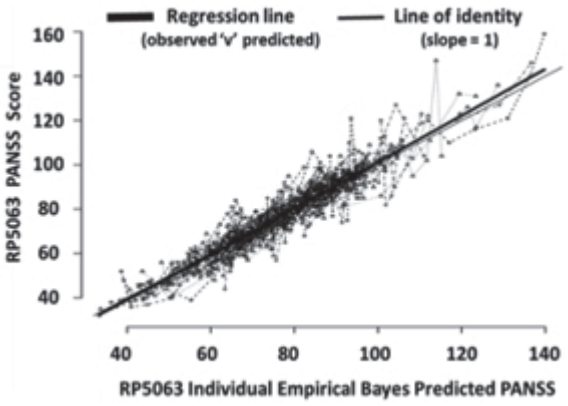
The analysis of brilaroxazine pharmacokinetic-pharmacodynamics relationship (PK-PD) reflected a linear, dose-proportional increase in exposure with dose and with no evidence of time dependency. Noteworthy was that the finding of brilaroxazine dose dependent drug exposure, reflected by Cmax and AUC. These parameters increased in direct proportion to dose irrespective of the population studied (e.g., healthy volunteers, patients with stable schizophrenia, patients with acute exacerbations of schizophrenia or schizoaffective disorder). In Phase 1 multi-dose study, drug levels approached steady-state after 120 h (5 days) of daily dosing, with doses between 10 and 100 mg with maximum steady-state concentrations of 70.1 and 696 ng/mL and AUCs of 1361 and 12526 ng*h/mL at the 10 and 100 mg dose, respectively.

We believe these findings indicate a potential for important clinical benefits. We believe the lack of excessive drug accumulation should translate to a potential clinical benefit of not needing titration of therapy. Such might be the case with other atypical antipsychotics (e.g., aripiprazole). We believe that lack of accumulation and the long half-life (~40-50 h) of brilaroxazine should translate easily to a once-daily dosing schedule. We believe this schedule is of clinical importance for the schizophrenic patient population since medication adherence, and missing doses with shorter half-life drugs can be a clinical issue leading to destabilization of clinical control. Such can lead to poor long-term functional outcomes in the treatment of schizophrenia. With brilaroxazine, if a patient misses a single dose or two, we believe sufficient plasma concentrations remain for clinical control. Furthermore, the pharmacokinetic profile of brilaroxazine is independent of gender, age, ethnicity, glomerular filtration rate, smoking, concomitant medications, geographic location of the clinical site, and type of schizophrenia (acute or stable) patients treated. These observations mean that clinicians may not need dose adjustments based on the patient population (Figure 7b).

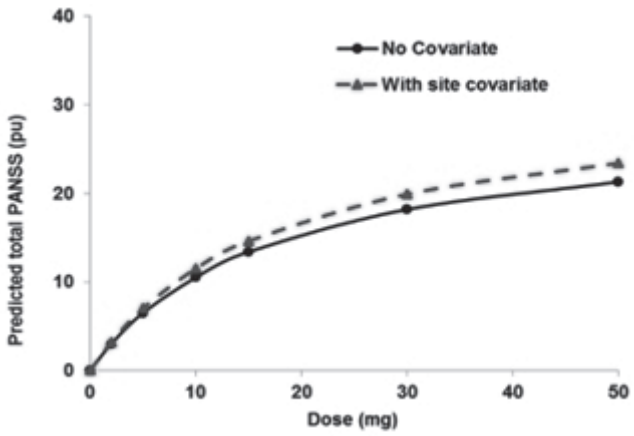
We performed the PK-PD modeling correlation with actual data using the observed and predicted PANSS demonstrating high predictability with relatively low variability. As shown in the graph below, both the regression line and line of identity are very close to each other. We believe this relationship indicates that the model is providing a very good fit (Figure 7a). The regression line is the line when one plots and regresses the observed data against the data predicted from the population model. The line of identity is when there is a perfect fit of the observed and predicted data (i.e., when each of the observed data is exactly equal to those of the corresponding predicted data, so the slope of the line is in exact unity). The dose-response curve showed that the total PANSS decrease was approaching its maximum response after a dose of approximately 15 mg. Thus, we believe brilaroxazine doses of 15 to 50 mg daily appear to be an effective clinical range of dosing (Figure 7b).

Figure 7. Brilaroxazine Phase 2 Clinical Study Pharmacokinetics and Pharmacodynamics Correlation

7A. Treatment PANSS vs. Predicted PANSS Scores



7B. Predicted Dose-Response Relationship

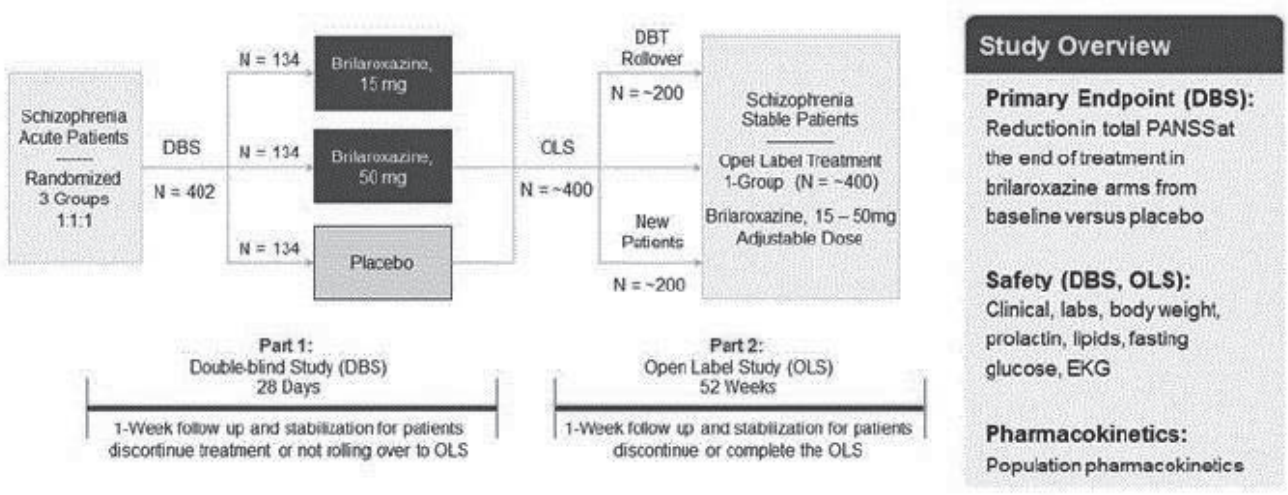


Brilaroxazine Phase 3 Studies in Schizophrenia

The Phase 1 and Phase 2 clinical experience in multiple populations (healthy volunteers, stable schizophrenia, and acute schizophrenia and schizoaffective disorder patients) reflect the promise of brilaroxazine as an addition to the treatment armamentarium of this disease. Both healthy volunteers and patients tolerated brilaroxazine well in both Phase 1 and 2 studies. The studies did not produce any cardiometabolic, cardiovascular, prolactin, or neurologic effects that would complicate current treatments. Investigators observed the early activity in Phase 1 after 10-days of dosing in stable patients and we believe that results from the Phase 2 trial may support the NDA for brilaroxazine, as brilaroxazine demonstrated significance versus placebo in Total PANSS Score at Day 28 as compared to baseline. The pharmacokinetics proved to be highly predictable and consistent between Phase 1 and 2 studies, participant type (healthy volunteer, patient), and racial characteristics (Caucasian, Black, Indian, and Japanese). Analyses showed substantive and relatively rapid oral absorption, linear, dose-proportional increases in Cmax and AUC, lack of undue accumulation, and a relatively long terminal half-life over 40 hours. We believe these findings translate to a straightforward once-daily dosing regimen with no need for titration or adjustments for the type of patient. These characteristics set the stage for further evaluation in Phase 3.

As part of the Phase 3 development plan in the end-of-Phase 2 (EOP2) meeting with the FDA in 2013, we presented the Phase 2 schizophrenia study results, discussed the Phase 3 development plans, and sought guidance from the FDA concerning the possibility of a superior safety label claim for brilaroxazine for the treatment of schizophrenia. We received a favorable response from the FDA, as the agency agreed to consider granting brilaroxazine a superior safety label claim for the treatment of schizophrenia if there is a positive outcome on a relevant endpoint in a pivotal Phase 3 study in schizophrenia. Further to support the superior safety label claim for brilaroxazine, the FDA agreed to waive the requirement to conduct a drug interaction clinical study with CYP2D6 inhibitors in Phase 3 development. We have accordingly planned Phase 3 development of brilaroxazine for acute and maintenance schizophrenia. We have completed the required regulatory compliant non-clinical studies. These include safety pharmacology studies, toxicology studies, and chemistry, manufacturing, and controls (CMC) development for initiating pivotal Phase 3 studies. Furthermore, the FDA has reviewed the results of these non-clinical studies and the Phase 3 protocols.

Figure 8. Brilaroxazine (RP503) Phase 3 RECOVER 1 Clinical Trial for Schizophrenia



On January 10, 2022, the FDA notified us that we may proceed with the RECOVER-1 Trial. On February 1, 2022, we announced that the first patients had been dosed in the RECOVER-1 Trial. On July 27, 2022, we announced that we had enrolled patients in 15 geographically diverse sites across the U.S. The RECOVER-1 Trial is a global Phase 3, randomized, double-blind, placebo-controlled, multicenter study designed to assess the safety and efficacy of brilaroxazine (RP5063) in 412 patients with acute schizophrenia compared to placebo. Brilaroxazine was administered at fixed doses of 15 mg or 50 mg once daily for 28 days. The primary endpoint was a decrease in Positive and Negative Symptoms Assessment total score compared to placebo from baseline to Day 28. Key secondary endpoints included clinical global impression (CGI) severity scale, positive and negative symptoms, social functioning and cognition. We enrolled approximately 60% of the patients in USA, 6% in Europe (Bulgaria) and 34% in Asia (India). On October 31, 2022, we announced over 30% enrollment in the RECOVER-1 Trial in the United States and the initiation of and ongoing enrollment in sites in Europe. The Company received regulatory approval for initiating the study in Asia (India) on October 11, 2022 and initiated multiple sites in India in November and December 2022. The RECOVER-1 Trial outline is described in Figure 8 above.

On October 30, 2023, we announced positive topline results and the successful completion of the RECOVER-1 Trial. The RECOVER-1 Trial successfully met its primary endpoint at the 50 mg dose, with brilaroxazine at that dose achieving a statistically significant and clinically meaningful 10.1-point reduction in Positive and Negative Syndrome Scale (PANSS) total score compared to placebo (-23.9 brilaroxazine 50 mg vs. -13.8 placebo, $p<0.001$) at week 4. Brilaroxazine also achieved statistically significant and clinically meaningful reductions in all major symptom domains and secondary endpoints at week 4 with the 50 mg dose vs. placebo. The 15 mg dose of brilaroxazine was numerically superior to placebo on the primary endpoint and most secondary endpoints, and reached statistical significance on two key secondary endpoints.

Key statistically significant and clinically meaningful improvements with brilaroxazine vs. placebo in patients with schizophrenia and a mean PANSS total score of 97-99 at baseline include:

Figure	Primary and Secondary Endpoints	Point Reduction/ Improvement for Brilaroxazine 50 mg vs. Placebo at Week 4	Cohen's d Effect Size	P Value
Figure 9	PANSS Total Score	10.1	*0.6*	*< 0.001*
Figure 10A	Positive Symptoms	2.8	*0.5*	*< 0.001*
Figure 10B	PANSS Excitement/Agitation	2.1	*0.5*	*< 0.001*
Figure 11A	Negative Symptoms (NS)	2.0	*0.4*	*0.003*
Figure 11B	NS Marder Factor	2.1	*0.4*	*0.002*
Figure 12A	PANSS Social Cognition	1.6	*0.5*	*< 0.001*
Figure 12B	Personal & Social Performance	6.3	*0.5*	*< 0.001*
Figure 13B	CGI-S Score	>1	*0.5*	*< 0.001*

Figure 9. Brilaroxazine Phase 3 RECOVER-1 Trial Efficacy Primary Endpoint: PANSS Total Score
10.1-point reduction in PANSS total score vs. placebo, p <0.001

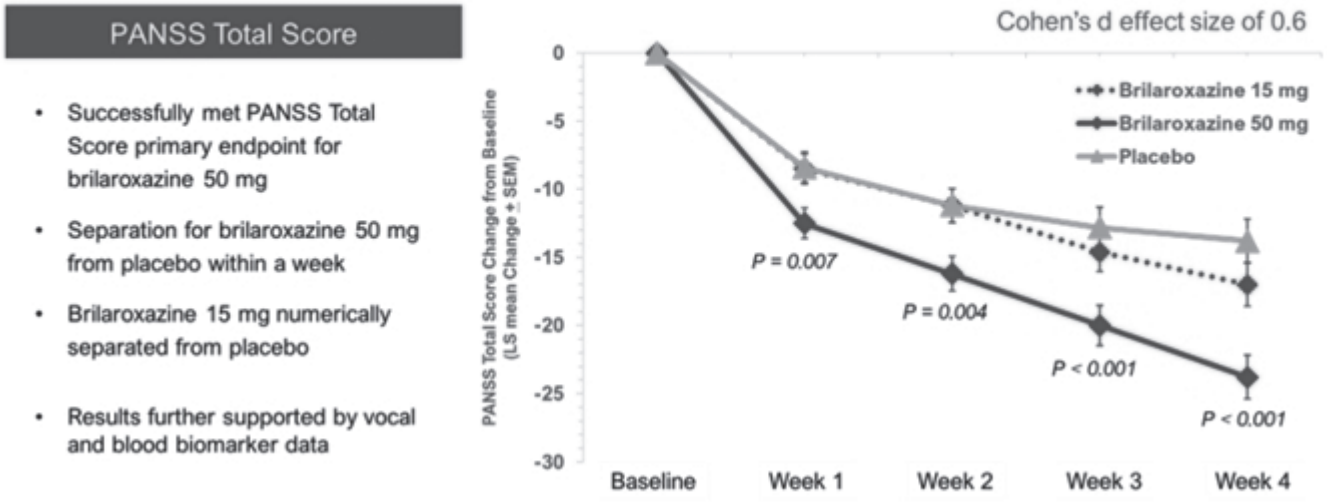


Figure 10. Brilaroxazine Phase 3 RECOVER-1 Trial Efficacy Secondary Endpoints: Positive Symptoms and Agitation/Excitement

Significant decrease in positive symptoms and agitation/excitement in brilaroxazine 50 mg vs. placebo

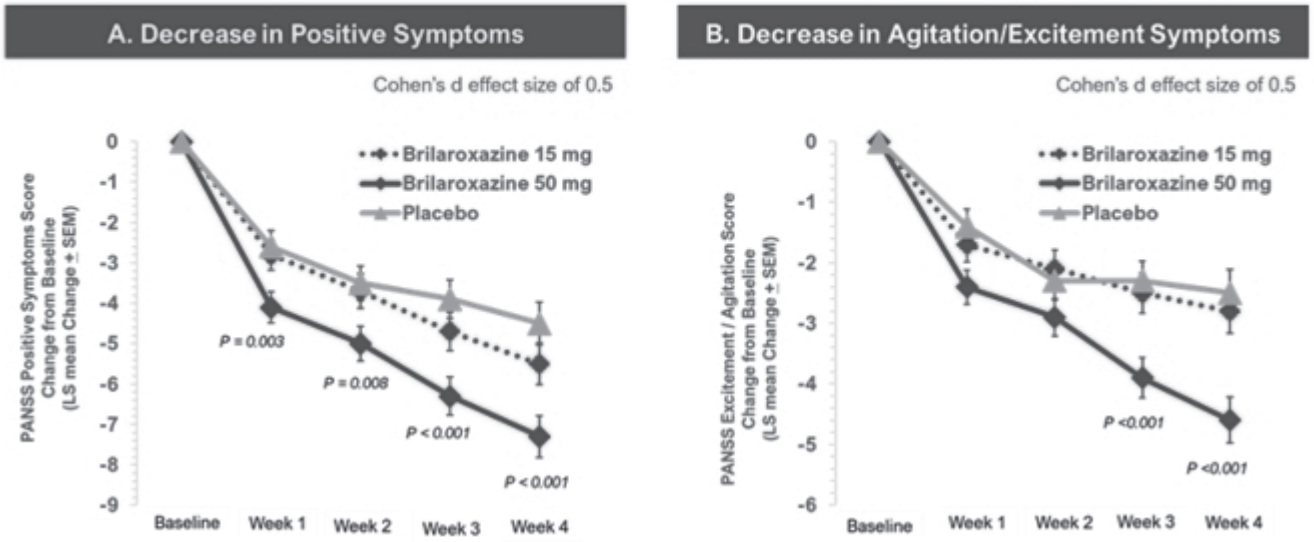


Figure 11. Brilaroxazine Phase 3 RECOVER-1 Trial Efficacy Secondary Endpoint: Negative Symptoms

Significant reduction in negative symptoms in brilaroxazine 50 mg vs. placebo

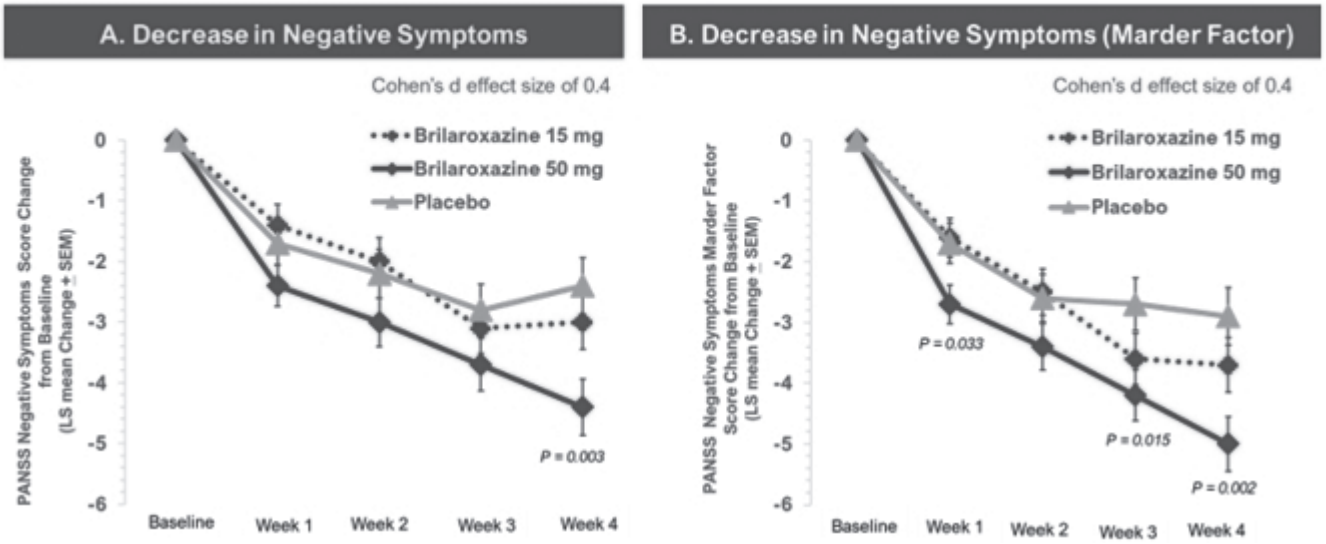


Figure 12. Brilaroxazine Phase 3 RECOVER-1 Trial Efficacy Secondary Endpoints Social Cognition and Social Functioning

Significant decrease in social cognition deficits and improvement in personal & social performance

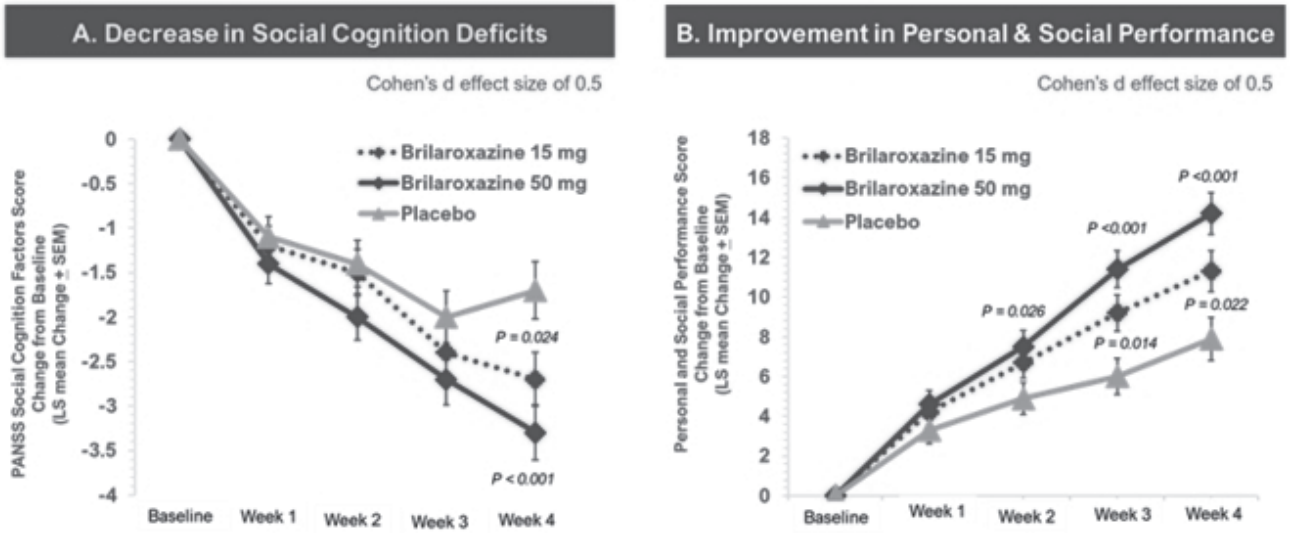
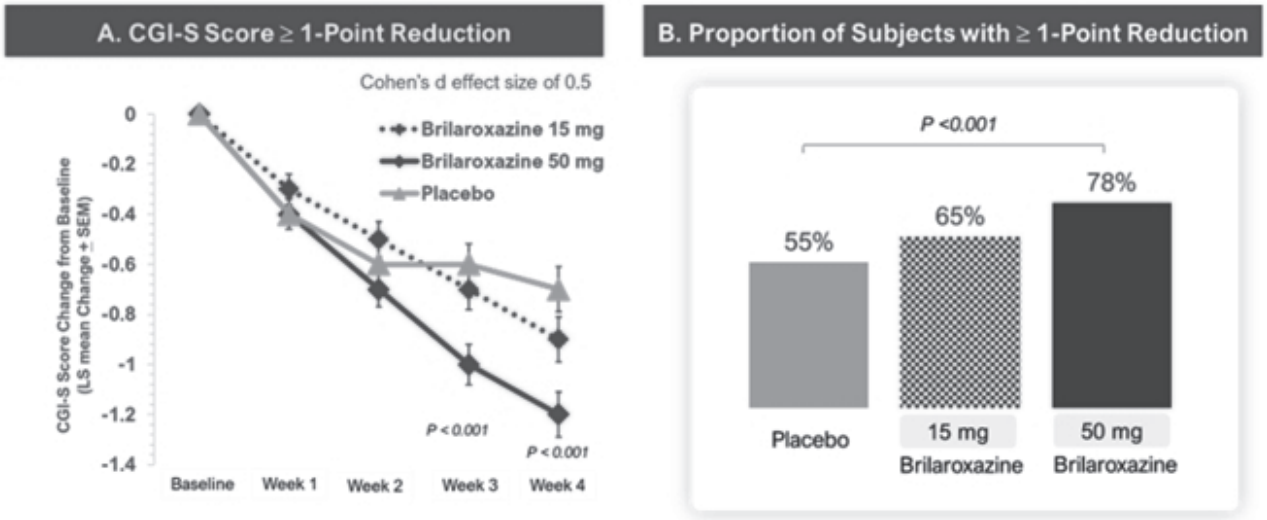


Figure 13. Brilaroxazine Phase 3 RECOVER-1 Trial Efficacy Secondary Endpoint: CGI-S Scores

≥1-Point reduction in CGI-S score in brilaroxazine 50 mg vs. placebo



Key clinical safety and tolerability findings of brilaroxazine support a safe and well-tolerated profile

- No drug related serious adverse events (SAEs) or treatment-emergent SAEs (TESAEs) observed or major safety concerns reported for brilaroxazine after 4 weeks of treatment;
- No incidence of suicidal ideation;
- No significant change in bodyweight and blood glucose levels compared to placebo;
- Significant decrease in cholesterol, LDL and increase in HDL compared to placebo;
- Significant decrease in prolactin and no change in thyroid levels compared to placebo;
- Akathisia and extrapyramidal symptoms <1% reported for brilaroxazine 50 mg and none for 15 mg; and
- Common brilaroxazine treatment-emergent adverse events (TEAEs) were headache (<6%) and somnolence (≤7.5%) generally transient in nature; and
- Low discontinuation rates with brilaroxazine that were less than placebo (16% in brilaroxazine 50mg and 19% in brilaroxazine 15mg vs. 22% placebo).

The clinical development plan for brilaroxazine consists of the completed positive Phase 2 REFRESH and Phase 3 RECOVER 1 trials, as well as an ongoing 1-year open label extension (OLE) trial evaluating the long-term safety and tolerability, and soon to be initiated registrational global, randomized 4-week RECOVER-2 Trial. We reported positive preliminary topline data from the OLE in December 2024, with the OLE expected to complete in Q2-2025, and we expect to initiate the registrational RECOVER-2 Trial in the second quarter of 2025, subject to receipt of additional financing, with topline readout anticipated in the third quarter of 2026. RECOVER-2 was originally designed as a 6-week study, but after discussion between Reviva and FDA, the agency has agreed that it can be conducted as a 4-week study. These data from our brilaroxazine clinical development plan will potentially support the planned NDA submission to the FDA in the fourth quarter of 2026.

OLE Trial - Enrollment Update and Topline Data

The OLE portion of the RECOVER Study is being conducted globally at multiple centers to assess the safety, and efficacy of brilaroxazine at flexible doses of 15, 30 or 50 mg, administered once daily for 52-weeks (1-year) in patients with stable schizophrenia. The OLE included both rollover participants from the double-blind portion of RECOVER study and de novo participants with stable schizophrenia. Long-term safety data from a minimum of 100 patients who have completed 1-year of treatment is a requirement for brilaroxazine's NDA submission to the FDA.

In November 2024, we provided the following enrollment update on our ongoing OLE evaluating the long-term safety and tolerability of brilaroxazine in patients with schizophrenia.

- Global trial progressing well;
- 108 patients have completed 1-year (12-month) of treatment;
- Over 250 patients have completed 6-months of treatment;
- Blood and digital biomarkers designed to independently support efficacy
- Long-term safety data from 100 patients who have completed 12 months of treatment is a requirement for brilaroxazine's NDA submission to the FDA; and

On December 16, 2024, we announced positive preliminary topline data from our OLE evaluating the long-term safety and tolerability of brilaroxazine in patients with schizophrenia. Administration of brilaroxazine once daily led to robust broad-spectrum efficacy that was sustained over 1 year. Brilaroxazine was generally well tolerated with no single side effect >5% and favorable compliance, with a discontinuation rate of 35% in the OLE part of this study. All three doses of brilaroxazine (15 mg, 30 mg and 50 mg) tested were efficacious and generally well-tolerated.

Key safety, efficacy and compliance findings for pooled analysis of brilaroxazine at 15, 30, and 50 mg include:

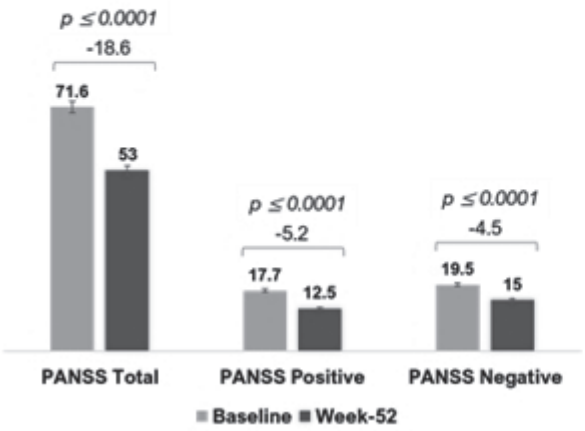
- A total number of 435 patients were enrolled in the OLE across three dose groups: 139 in brilaroxazine 15 mg, 155 in brilaroxazine 30mg and 141 in brilaroxazine 50mg
- 156 (35.86%) rollover participants from the double-blind portion of the Phase 3 trial, while 279 (64.13%) de novo participants enrolled in the OLE
- Preliminary efficacy results are presented for 113 patients who completed 52 weeks (1 year) of treatment; preliminary safety results are presented for all 435 patients who enrolled in the OLE, including patients that are still participating in the trial

Brilaroxazine across doses improved major symptom domains of schizophrenia after 1-year of treatment:

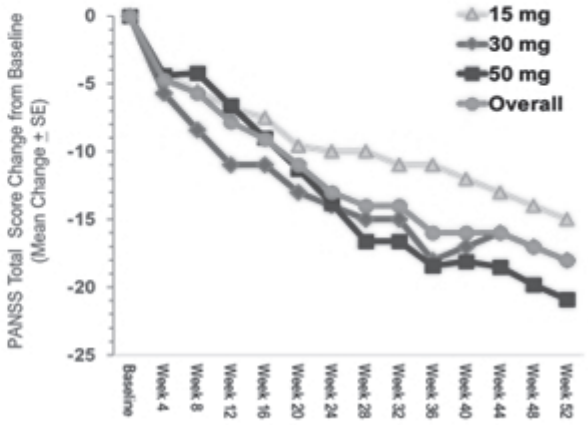
- Dose dependent efficacy at the 15, 30, and 50 mg doses was observed, with decreases in PANSS total scores of -15.2, -18.6 and -20.8 points, respectively, from baseline to end-of-treatment at 52 -week (1-year)
- Pooled data of brilaroxazine at the 15, 30, and 50 mg doses (N = 113) demonstrated clinically meaningful and sustained long-term (1-year) efficacy for schizophrenia with a significant decrease in PANSS total scores, PANSS positive symptoms, and PANSS negative symptoms compared to baseline
    - PANSS Total scores: 18.6-point decrease (71.6 → 53), $p \leq 0.0001$
    - PANSS Positive Symptoms: 5.2-point decrease (17.7 → 12.5), $p \leq 0.0001$
    - PANSS Negative Symptoms: 4.5-point decrease (19.5 → 15.0), $p \leq 0.0001$

Figure 14. Brilaroxazine Phase 3 OLE Trial Efficacy Results

A. Change in PANSS Total, and PANSS Positive and Negative Symptom Scores from Baseline to Week-52 (pooled analysis of brilaroxazine 15, 30 & 50mg groups



B. Change in PANSS Total Scores from Baseline to Week-52 in Brilaroxazine 15, 30, & 50 mg groups



- Brilaroxazine demonstrated strong sustained efficacy from acute through maintenance treatment over 1 -year with a decrease in PANSS Total score in rollover patients from the double-blind portion of the trial
    - ≥30-point decrease of PANSS total in 86.76% of patients
    - ≥40-point decrease of PANSS total in 64.70% of patients
    - ≥50-point decrease of PANSS total in 33.82% of patients

Long-term clinical safety, tolerability and adherence findings of brilaroxazine administered for up to one year support a well-tolerated safety profile:

- 15.2% of participants reported at least one treatment-related adverse event (TRAE), which were mostly mild (12.2%) or moderate (3%) in severity and transient in nature
- Most common TRAEs ≥1% were weight increase (3.2%), insomnia (1.8%) and somnolence (1.6%)
- Brilaroxazine was not associated with any clinically meaningful changes in movement disorder scales over 1 -year treatment
- No drug-related serious adverse events (SAEs) observed or major safety concerns reported for brilaroxazine after up to 1 -year of treatment; 3 serious adverse events were reported and none were related to brilaroxazine treatment
- Treatment discontinuation rate of 35% reported in this OLE, primarily due to withdrawal of consent (22%), participant lost to follow up (7%), and treatment-related adverse events (1.6%)

Collectively, the findings from the OLE (52-week/1-year) portion of the Phase 3 RECOVER study further strengthen the safety, efficacy and treatment adherence findings from the double-blind (4-week) portion of RECOVER.

Brilaroxazine Clinical Development for Bipolar Disorder (BD), Major Depressive Disorder (MDD), and Attention-Deficit/Hyperactivity Disorder (ADHD)

Like schizophrenia, BD, MDD, and ADHD are major neuropsychiatric diseases. These neuropsychiatric diseases exhibit distinct symptoms yet share varying degrees of overlapping conditions that include psychosis, depression, and cognitive impairments. BD, a medical illness with substantial morbidity and mortality, involves episodic, recurrent mania or hypomania, and major depression. An article published in 2018 in the journal Therapeutic Advances in Psychopharmacology estimated that the global prevalence of bipolar spectrum disorders is approximately 2.4%, with approximately 0.6% for bipolar I and approximately 0.4% for bipolar II. The same journal article indicates prevalence of bipolar I in the U.S. is 1%, slightly higher than in other countries. Similarly, MDD is a common, chronic, recurrent, and debilitating psychiatric condition, leading to significant impairments in personal functional capacities. The National Institute of Mental Health (NIMH) estimated the prevalence of MDD among U.S. adults aged 18 or older at 17.3 million in 2017. NIMH also indicated the prevalence was higher among females (8.7%) compared to males (5.3%). ADHD is a common developmental disorder in children and often continues into adulthood. The prevalence of ADHD in children is 5-12% worldwide, according to an article published in 2016 in the Journal of Advanced Pharmaceutical Technology & Research. ADHD has a high rate of comorbid psychiatric disorders.

The clinical community also uses the antipsychotic drugs (e.g., olanzapine, risperidone, quetiapine, and aripiprazole) for the treatment of BD, MDD, and/or ADHD. All these antipsychotics display pharmacological activities for dopamine (D) and serotonin (5HT) receptors. The majority are selective for D2 and 5HT2A receptors, and may also be active for one or more of D4, 5HT1A, 5HT2B, and 5HT7 receptors. Brilaroxazine exhibits potent activity for D2 and 5HT2A receptors, and each of D4, 5HT1A, 5HT2B, and 5HT7 receptors are implicated as pharmacological targets for depression and cognitive impairment conditions.

Subject to the receipt of additional financing, we may proceed with Phase 2 studies for brilaroxazine in BD, MDD, and ADHD, potentially as early as the first half of 2026.

Brilaroxazine Clinical Development for Psychosis and Behavioral Symptoms in Alzheimer's Disease (BPSD), and Parkinson's Disease Psychosis (PDP)

Patients with Alzheimer's disease (AD) manifest not only progressive memory impairment, cognitive deficits, and functional alterations but also a variety of neuropsychiatric symptoms (agitation, aggression, hallucinations, and delusions). An article published in 2002 in the journal Archives of General Psychiatry (now JAMA Psychiatry) states these symptoms ultimately affect up to 75% of individuals with dementia and, once present, sustain, or recur. Similarly, patients with Parkinson's disease also suffer from neuropsychiatric symptoms. There are very limited pharmacological treatment options for managing psychotic and behavioral symptoms in Alzheimer's and Parkinson's diseases. Without an approved drug, clinicians often manage the psychosis and behavioral symptoms in Alzheimer's disease with antipsychotics (e.g., quetiapine and olanzapine). Primavanserin (Nuplazid), a serotonin 5HT2A inverse agonist, is the only FDA approved treatment for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. However, clinicians do use some antipsychotics (e.g., quetiapine, and olanzapine) as an off-label treatment.

Subject to the receipt of additional financing, we may also continue the clinical development of brilaroxazine for the treatment of BPSD and PDP.

DEVELOPMENT OF BRILAROXAZINE FOR RESPIRATORY DISEASES

Development of brilaroxazine for Pulmonary Arterial Hypertension (PAH)

PAH is a progressive, debilitating condition characterized by pulmonary vascular resistance leading to right ventricular failure and death. According to an article published in 2016 in the journal The Lancet Respiratory Medicine, the global prevalence of PAH is estimated at 6.6 – 26.0 cases per million with 1.1 – 7.6 incidences per million adults per year. The same article indicates PAH is frequently diagnosed in older patients, particularly those 65 years and older. As presented in 2020, the National Organization for Rare Disorders ("NORD") estimates PAH occurs 3 – 5 times more frequently in females than in males, and it tends to affect females between the ages of 30 and 60. Pursuant to a study published in 2012, post-diagnosis of PAH, survival rates are approximately 1 year in 85%, 3 years in 68%, and 5 years in 57% of patients, respectively (Benza RL et al, CHEST 2012, 142(2):448-456).

PAH occurs when the pulmonary arteries have narrowed, thickened, or become blocked due to the constricting and remodeling of the pulmonary vasculature. Endothelial dysfunction occurs early in the disease pathogenesis. Such pathology leads to the proliferation of the endothelium and smooth muscle tissue, the remodeling of pulmonary arteriole walls, the impaired production of vasodilators, and the overexpression of vasoconstrictors. Remodeling can involve a variety of smooth muscle (e.g., hyperplasia, medial hypertrophy, perivascular fibrosis) and other extrinsic pathologic changes (e.g., microthrombosis, inflammatory cell infiltration, angioproliferative plexiform lesions).

Current treatment involves influencing smooth muscle tone: 1 — inhibition of phosphodiesterase 5 (PDE-5) (e.g., sildenafil) and nitric oxide; 2 — antagonizing endothelin (e.g., bosentan); and 3 — providing exogenous prostacyclins (e.g., epoprostenol, iloprost, treprostinil) to address the reduced production of prostaglandin I2. Such treatments can reduce symptoms, improve the performance of activities of daily living, delay disease progression, and improve survival somewhat (e.g., epoprostenol). However, they fail to stem the ongoing cytoproliferative processes that significantly modify the pulmonary vascular structure and lead to progressive disease and/or the need for lung transplantation.

Serotonin (5-hydroxytryptamine; 5HT) plays a role in both the proliferative and functional components of the pathogenesis of PAH, which involve a variety of contributing factors, including inflammatory cytokines and chemokines. Pulmonary arteries express several 5HT receptors, including the 5HT2A, 5HT2B, and 5HT7. The presence of 5HT in the pulmonary circulation activates vascular smooth muscle (VSM), 5HT2A and 5HT2B receptors, and SERT to cause constriction, the proliferation of pulmonary vascular smooth muscle cells, and fibroblast proliferation. Coupled with stimulating the transforming growth factor β pathway, the 5HT pathway facilitates cell proliferation and vascular remodeling. These changes lead to the thickening of the medial layer. These accompany the narrowing and the remodeling of the pulmonary artery. Together these define the characteristics of PAH.

Brilaroxazine is a novel candidate for the management of PAH. As a potent antagonist of the 5-HT receptor, it possesses a high binding affinity for several relevant targets associated with PAH. These include 5HT2A (2.5 nM), 5HT2B (0.19 nM), and 5HT7 (2.7 nM), as well as a moderate affinity for SERT (107 nM) in preclinical models.

Brilaroxazine Preclinical Development for PAH

The FDA designated brilaroxazine as an orphan drug for the treatment of PAH in 2016. The agency based its decision on encouraging preclinical results with brilaroxazine in PAH, including disease-modifying antiproliferative effects. Two studies using the monocrotaline (MCT) and Sugen hypoxia (Su-Hx) models evaluated the effectiveness of brilaroxazine as monotherapy. Further, an additional study with the MCT model assessed this compound's effectiveness as an adjunct with several other standard treatments for PAH.

The monotherapy MCT-induced model involved a 28-day treatment on single-agent brilaroxazine. On Day 0, adult male Wistar–Kyoto rats, randomized into five groups of 10 animals, received a single intravenous 60-mg/kg MCT dose. Subsequently, on Days 0 to 27, the rats were gavaged twice daily (BID) with vehicle (MCT+Veh; 5% glucose solution), brilaroxazine (1, 3, or 10 mg/kg), or sildenafil (50 mg/kg). On Day 28, during terminal surgery, investigators obtained blood samples, hemodynamic readings, and harvested tissues.

In this study, brilaroxazine produced significant functional and structural changes, as compared with those in the MCT+Veh group. Functionally, brilaroxazine displayed healthier pulmonary hemodynamic parameters, translating to reduced right ventricle (R.V.) hypertrophy and suggesting greater pulmonary vascular elasticity. This activity led to improved respiratory resistance and hemoglobin oxygen saturation, as compared with PAH animals without treatment. Structurally, brilaroxazine appeared to prevent the remodeling of the smooth muscle cells in the pulmonary vasculature. The 10 mg dose prevented vascular intimal thickening (endothelial and smooth muscle hyperplasia, and the multiplication of vascular smooth muscle cells) in the smaller vessels, mostly non-muscular in healthy animals. In exploring the cytokine response, the study found that all doses of brilaroxazine produced lower levels of tumor necrosis factor (TNF) α and interleukin (IL) β, and facilitated a significant reduction of IL-6 ($p<0.05$). These observations suggest an antiproliferative capacity.

In the SuHx-induced PAH study, investigators gave brilaroxazine treatment for 21 days. On Day 0, 4 groups of adult male Wistar–Kyoto rats received a subcutaneous injection of Sugen 5416 (20 mg/kg). Investigators kept them at FiO2 of 10% (Days 0 – 21) and 21% (Days 22 – 35). During the treatment period starting at Day 14, rats were gavaged twice daily (BID) with vehicle (SuHx+Veh; 5% glucose solution), brilaroxazine (10 or 20 mg/kg; RP-10 and RP-20, respectively), or sildenafil 50 mg) on Days 14 to 35. On Day 35, during terminal surgery, investigators obtained blood samples, hemodynamic readings, and harvested tissues.

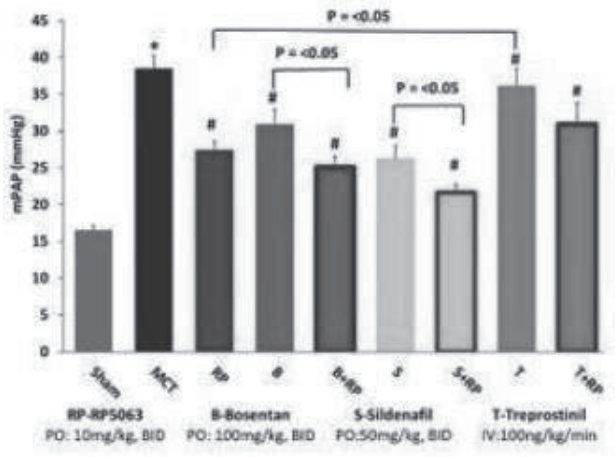
Both doses of brilaroxazine and sildenafil produced a significant effect on functional and structural parameters, as compared with the induced group treated with vehicle (SuHx+Veh). Functionally, brilaroxazine improved pulmonary hemodynamics and respiratory function, resulting in higher oxygen saturation, as compared to non-treated, Sugen-induced animals. Structurally, brilaroxazine decreased small-vessel wall thickness and the percentage of muscular vessels. Most significantly, brilaroxazine limited arterial obliteration and prevented the formation of plexiform lesions. These observations suggest that the compound might exert antiproliferative effects and, potentially, a disease-modifying capacity. Concerning the cytokine effect, both brilaroxazine dose groups reflect lower levels of leukotriene-B4 at Days 21, 28, and 35.

Considering the initial observations with brilaroxazine as a single-agent treatment in both the MCT and SuHx models in rats, we undertook an additional MCT study with this compound to evaluate its role as adjunctive therapy to standard PAH treatments (Bhat et al., 2018). In the same MCT model as previously described, investigators examined brilaroxazine as monotherapy and as an adjunct to current standards of PAH care (bosentan, sildenafil, treprostinil).

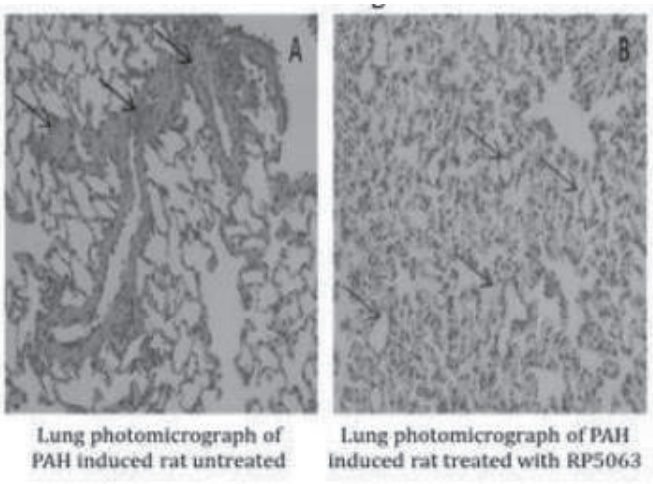
As a single agent, brilaroxazine produced functional and structural effects seen in the MCT+Veh group and was consistent with those seen in the initial monotherapy MCT study. Furthermore, these effects were like (and in some cases, better than) the standard treatments. As an adjunct to all treatments, brilaroxazine significantly ($p<0.05$) lowered mean and systolic pulmonary artery pressures and R.V. systolic pressure, and improved oxygen saturation, as compared with the untreated, induced animals. The combination of brilaroxazine and sildenafil displayed the most consistent and robust effects. The most notable was on pulmonary hemodynamics, respiratory parameters, and histopathologic changes.

Figure 15. Effect of Brilaroxazine Treatment in MCT (15A) and Sugen-Hypoxia (15B) Induced PAH in Rats

A. Treatment Effects on PAH



B. Treatment Effects on Lung Vascular Structure



Brilaroxazine Clinical Development for PAH

We had a pre-investigational new drug application ("IND") meeting with the FDA in August 2017, in which we presented brilaroxazine preclinical development data including efficacy results for PAH in rodent models, the data of regulatory compliant non-clinical studies (e.g., safety pharmacology studies, toxicology studies, and Chemistry, Manufacturing, and Controls (CMC) development), and the data of clinical Phase 1 studies. We discussed the Phase 2 clinical development plan with FDA and sought the agency's guidance for our clinical development plan for a disease modifying label claim based on the positive specific clinical outcome. Pursuant to the agency's guidance, we designed our clinical development plan to seek to obtain a disease modifying label claim.

Subject to the receipt of additional financing, we may proceed with a Phase 2 clinical trial for brilaroxazine in PAH.

Development of Brilaroxazine for Idiopathic Pulmonary Fibrosis (IPF)

IPF is a chronic, progressive, and debilitating lung disease. In 2019, Medscape reported the worldwide prevalence of IPF is estimated at 20 cases per 100,000 persons for males and 13 cases per 100,000 persons for females. Medscape also reported that in the U.S., the prevalence among individuals aged 50 years or older ranges from 27.9 to 63 cases per 100,000. Medscape also reported, for patients suffering from IPF, the estimated mean survival is 2-5 years from the time of diagnosis and that mortality rates are estimated at 64.3 deaths per million in men and 58.4 deaths per million in women.

IPF involves chronic inflammation and progressive fibrosis of the alveoli. This pathology leads to destroyed lung architecture, reduced lung capacity, impaired oxygenation, and a decline in lung function.

Treatment involves early referral for lung transplantation, palliative care, and clinical trials. Limitations exist with various interventions, including commonly used agents (e.g., corticosteroids and immunosuppressants), and current guidelines do not support them. Clinical studies of two Food and Drug Administration approved treatments — Nintedanib (Ofev), and Pirfenidone (Esbriet) — have not demonstrated significant relief to functional decline and disease progression (Maher & Strek, Respiratory Research (2019)). Hence, we believe survival continues as an unmet need.

Various studies have implicated 5HT in the pathophysiology of IPF. It exerts a vasoactive effect on pulmonary arteries and stimulates lung myofibroblast actions. Pulmonary 5HT appears to mediate effects through 5-HT2A/2B/7 receptors.

Brilaroxazine may be a new candidate for the management of IPF. As a potent antagonist of the 5HT receptor, it possesses a high binding affinity for several relevant targets associated with IPF. These include 5HT2A (2.5 nM), 5HT2B (0.19 nM), and 5HT7 (2.7 nM), as well as a moderate affinity for SERT (107 nM) in preclinical models.

Brilaroxazine Preclinical Development for IPF

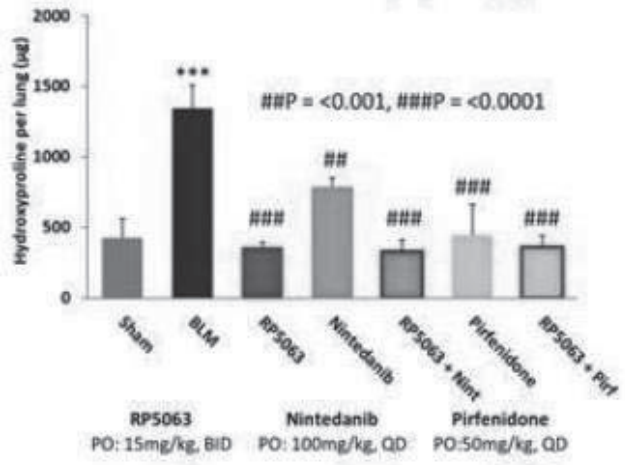
A bleomycin (BLM)-induced model involved a 21-day protocol using 34 Sprague Dawley rats divided into four groups- Group 1 (no induction, vehicle control), Group 2 (induction, vehicle control), Group 3 (induction, brilaroxazine, 15 mg/kg, intervention at Day 1), and Group 4 (induction, brilaroxazine, 15 mg/kg, intervention at Day 10). On Day 21, during terminal surgery, investigators obtained blood samples, hemodynamic readings, harvested tissues, and bronchoalveolar lavage fluid (BALF) samples. The histological analysis to evaluate effects on fibrosis involved several tests. Tissue stained with Masson's Trichrome and visualized using a scanner to determine the percentage of the fibrotic tissue, reflective of excessive collagen disposition in the lung. A colorimetric assay assessed the content of hydroxyproline, an amino acid for fibrillar collagens, from the right lung tissue sample. Finally, cytokine analysis of the BALF samples evaluated the effects on Macrophage inflammatory protein 1 (MIP1), Monocyte chemoattractant protein 1 (MCP1), Interleukin (IL)-6, Interferon gamma-induced protein 10 (IP10) and RANTES levels.

Compared with the bleomycin-induced vehicle group, the use of brilaroxazine at Day 0 and Day 10 sustained animal survival at 90.5% and 89.5%, respectively ($P<0.05$). Furthermore, animals maintained their weight with both brilaroxazine interventions, as compared with the vehicle group ($P<0.01$). Animals in both brilaroxazine groups restored cardiac output, with the Day 0 group displaying a significant effect as compared to those treated with vehicle ($P<0.01$). The Day 0 brilaroxazine also normalized pulse pressure.

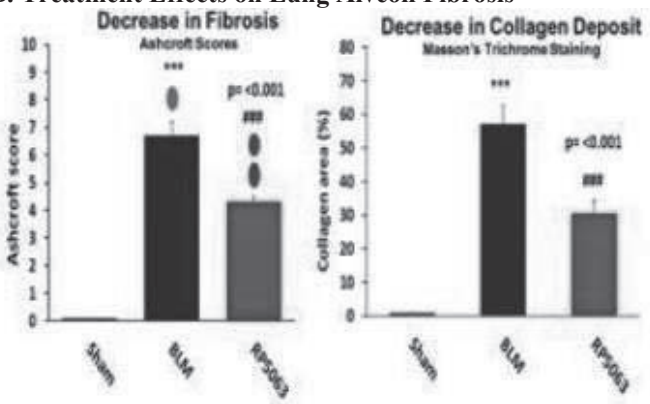
Brilaroxazine treatment influenced multiple functional, histological, and cytokine parameters reflective of pulmonary fibrosis. Animals in the brilaroxazine Day 0 group displayed a significant reduction in respiratory resistance ($P<0.05$). Those in Day 10 group showed improvement ($P=0.10$). Both brilaroxazine interventions produced a significant diminution in the concentration of hydroxyproline ($P<0.05$, Day 0; $P<0.01$, Day 10). Lung weights, which increased in the vehicle group suggesting the presence of edema, were significantly lower in the brilaroxazine Day 0 group ($P<0.05$). From the BALF samples, total cell count (inflammation) was lower in both brilaroxazine groups ($P<0.05$), as well as total protein content (edema) in the brilaroxazine Day 0 group ($P<0.05$). Ashcroft Score from stained lung tissue reflected a significant reduction in the lung parenchymal fibrotic changes in the Day 0 group ($P<0.001$). Concerning the percent of fibrosis areas measured with Masson's trichrome staining, the Day 0 brilaroxazine group significantly reduced these changes ($P<0.001$), as compared with the vehicle group (Figure 9B). Furthermore, the Day 0 group showed significantly improved blood oxygen levels ($P<0.05$). Both groups induced a diminution of blood lactate levels ($P<0.01$, Day 0; $P<0.05$, Day 5). Finally, both brilaroxazine groups reduced proinflammatory and fibrotic cytokines, with significant effects on MCP-1 ($P<0.05$, Day 0), IP10 ($P<0.01$, both brilaroxazine interventions), and RANTES ($P<0.01$, both brilaroxazine interventions).

Figure 16. Effect of Brilaroxazine (RP5063) as a Monotherapy and Co-administered with Standard of Care Nintedanib and Pirfenidone in Bleomycin (BLM) Induced IPF in Rats

A. Treatment Effects on Lung Hydroxyproline



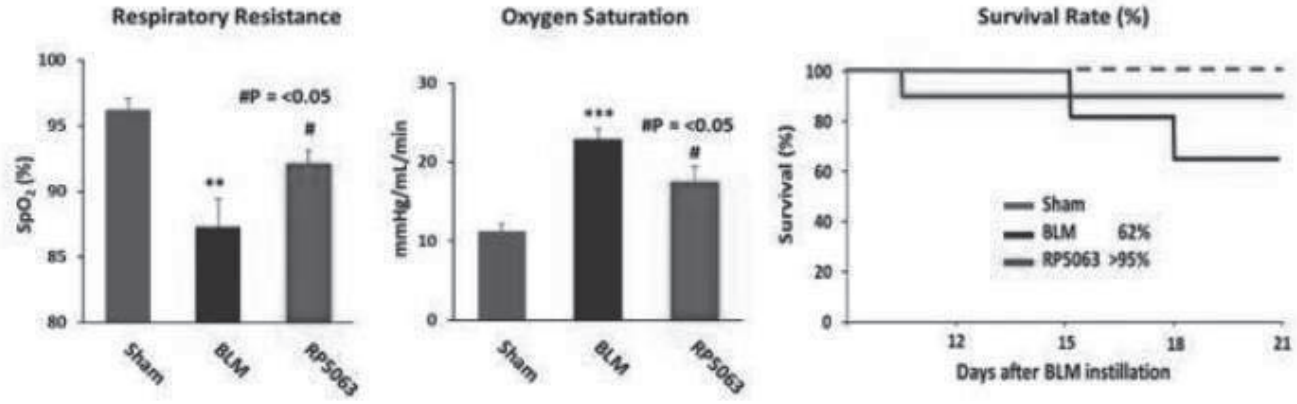
B. Treatment Effects on Lung Alveoli Fibrosis



RP5063, PO: 15mg/kg, BID

A follow-up preclinical study utilized the same BLM-induced model and methods. This study evaluated the effect of brilaroxazine (15 mg/kg twice daily) in combination with either nintedanib or pirfenidone (both dosed at 100 mg/kg once daily). Both nintedanib and pirfenidone are the current standard of care for patients with IPF. Single-agent treatment with nintedanib and pirfenidone (both dosed at 100 mg/kg once daily) served as controls. Treatment started on Day 7 following BLM-induction and continued until Day 20. Terminal surgery occurred on Day 21, in which harvesting of lung tissue and collecting of BALF occurred. Similar histological investigations evaluated the effects of treatment on mitigating the development of fibrosis via BLM-induction.

Figure 17. Effect of Brilaroxazine Treatment in Bleomycin (BLM) Induced IPF in Rats



Brilaroxazine, as an adjunct to nintedanib and pirfenidone, significantly augmented the functional and histological effects of nintedanib and pirfenidone, two standard treatments for IPF, as evidenced by reduction in hydroxyproline level (Fig 10A) and fibrosis (Fig 10B) in the lungs. The brilaroxazine treatment demonstrated a reduction in respiratory resistance ($P<0.05$), an increase in blood oxygenation $P<0.05$), and an improvement in survival rate (95%), as compared with vehicle control (62%) (Figure 11). Furthermore, brilaroxazine, as an adjunct, mitigated lung fibrosis, and collagen disposition, the hallmarks of pulmonary fibrosis, as evidenced by the significantly ($P<0.001$) reduced concentration of hydroxyproline in the lungs produced by the treatment combinations (Figure 9A), as compared with vehicle control.

Brilaroxazine (RP5063) Clinical Development for IPF

The FDA granted orphan drug designation to brilaroxazine for the treatment of IPF in 2018. We had a pre-IND meeting with the FDA, in which we presented brilaroxazine preclinical development data including efficacy results for IPF in rodent models, the data of regulatory compliant non-clinical studies (e.g., safety pharmacology studies, toxicology studies, and Chemistry, Manufacturing, and Controls (CMC) development), and the data of clinical Phase 1 studies. We have discussed the Phase 2 clinical development plan with FDA and sought the agency's guidance for our clinical development plan for a disease modifying label claim based on the positive specific clinical outcome. Pursuant to the agency's guidance, we designed our clinical development plan to seek to obtain a disease modifying label claim.

Subject to the receipt of additional financing, we may also develop the clinical protocols and proceed with a Phase 2 clinical trial for brilaroxazine in IPF.

DEVELOPMENT OF RP1208 FOR DEPRESSION AND OBESITY

About RP1208

Our RP1208 drug candidate, a new chemical entity (NCE), is a novel triple reuptake inhibitor (TRI) which we believe is ready to be in IND enabling studies for depression and ready to be in animal efficacy studies for obesity, following the receipt of adequate additional financing. We possess a granted composition of matter patent for RP1208 in the USA, Europe, and several other countries.

Depression is a debilitating illness characterized by symptoms like anhedonia, depressed mood leading to suicidal thoughts, impaired cognitive functions, slowing of speech, and other actions. The NIMH estimated the prevalence of MDD among U.S. adults aged 18 or older at 17.3 million in 2017. NIMH also indicated the prevalence was higher among females (8.7%) compared to males (5.3%). Although there are many antidepressants in the market, an article published in 2003 indicates clinicians believe that approximately 50 – 60% of patients do not respond to the therapy (Fava M. Biological Psychiatry 2003, 53:649-659), which we believe reflects an unmet need to develop novel therapeutics to combat depression. The persistence of anhedonia originating from a depressed dopaminergic activity is one of the most treatment-resistant symptoms of depression. Currently, six major classes of antidepressant drugs, which target mainly monoamine transporters serotonin (SERT) and norepinephrine transporters (NET), are available. Therefore, though leaders have hypothesized that triple reuptake inhibitors (TRIs), with their potency to block dopamine reuptake by blocking dopamine transporter (DAT), in addition to serotonin transporter (SERT) and norepinephrine transporter (NET) should produce higher efficacy.

Triple reuptake inhibitor active compounds stimulate satiety and act as an appetite suppressant. Pharmacological studies have demonstrated that stimulated monoaminergic activity induces profound effects on feeding behaviors and, thus, energy intake. Furthermore, they have shown that agents that enhance synaptic levels of norepinephrine (NE), serotonin (5HT), or dopamine (DA) by stimulating release or reducing reuptake can decrease feeding and weight gain.

We have conducted several *in vitro* and *in vivo* studies on RP1208. In the radioligand binding assays, it has shown potent binding affinities for monoamine transporters DAT (Ki = 1.2 nM), SERT (0.8 nM), and NET (11 nM). Studies using in vitro functional assays assessed the functional activity of RP1208 for monoamine transporters. RP1208 showed potent functional inhibitory activities for monoamine transporters with IC50 values <1 nM for DAT, 6.6 nM for SERT, and 2 nM for NET. In the in vivo studies, RP1208 has shown acceptable bioavailability of 9% ($t_{½}$=2.3 h) in rat and 50% ($t_{½}$=13.1 h) in dog models. RP1208 rapidly and extensively distributes into tissues, including the brain with a brain:plasma ratio of ~1:1 (rat), despite high plasma protein binding (>99%).

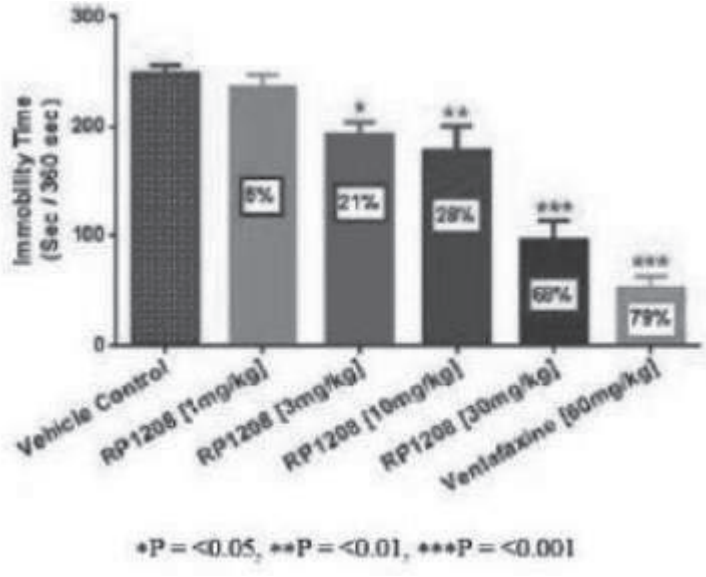
RP1208 Preclinical Studies for Depression and Obesity

We evaluated the antidepressant activity of RP1208 in the tail-suspension test in the mouse model. The tail-suspension test is a mouse behavioral test useful in the screening of potential antidepressant drugs, and assessing other manipulations that investigators expect to affect depression-related behaviors. Mice are suspended by their tails with tape, in such a position that it cannot escape or hold on to nearby surfaces. During this test, typically six minutes in duration, the resulting escape-oriented behaviors are quantified. A tail-suspension test is a valuable tool in drug discovery for high-throughput screening of prospective antidepressant compounds.

The tail-suspension test in male BALB/c mice with 1, 3, 10, and 30mg/kg doses evaluated the antidepressant activity of RP1208. Venlafaxine, an approved antipsychotic drug, 60 mg/kg, was the positive control in the study. RP1208 has shown statistically robust significant reduction in immobility time at 3 mg/kg ($p = <0.05$), 10 mg/kg ($p = <0.01$), and 30 mg/kg ($p = <0.001$) doses. The antidepressant activity of RP1208, as measured by reduction in immobility time at different dose levels, was dose-dependent with no adverse effects (Figure 18).

Subject to the receipt of additional financing, we may also advance the development of RP1208 for depression and obesity.

Figure 18. Effect of RP1208 in Immobility Time in Male BALB/c Mice in Tail Suspension Test

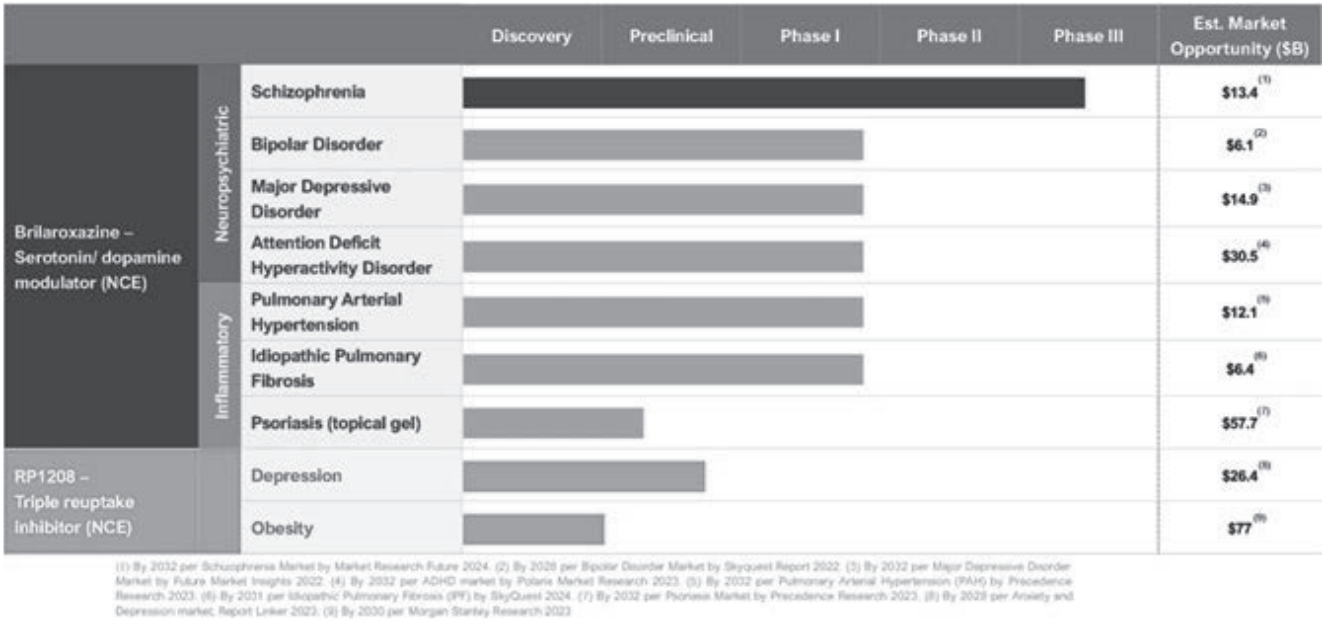


MARKET

Neuropsychiatric Diseases Schizophrenia, Bipolar Disorder (BD), Major Depressive Disorder (MDD), and Attention-Deficit/Hyperactivity Disorder (ADHD)

Schizophrenia, BD, and MDD are major neuropsychiatric diseases often chronic in nature. These neuropsychiatric diseases exhibit distinct symptoms yet share varying degrees of overlapping conditions that include psychosis, depression, and cognitive impairments. Schizophrenia is a complex debilitating psychiatric disease involving a mix of positive and negative symptoms, along with mood disorder (e.g. depression and anxiety) and cognitive impairment. As presented in 2020, SARDAA estimates schizophrenia can be found in approximately 1.1% of the world's population, regardless of racial, ethnic or economic background, with approximately 3.5 million people diagnosed in the U.S. Schizophrenia imposes substantial burden on patients, their families and overall society. Treatment and other economic costs due to schizophrenia are enormous, estimated by SARDAA to be between $32.5 and $65 billion annually. Antipsychotic drugs are the first-line treatment for patients with schizophrenia. Increasing awareness among patients and physicians in the field of mental health, particularly schizophrenia is likely to increase the penetration of antipsychotic drugs in the market. Currently, second and third-generation antipsychotics capture significant market share. Pipeline drugs undergoing clinical trials intend to block specific subtypes of serotonin and dopamine receptors which would help to mitigate the symptoms and address unmet medical needs. According to a 2024 report from Market Research Future, the estimated global drugs market size for schizophrenia is anticipated to reach approximately $13.4 billion by 2032 (Figure 13).

Figure 13. Estimated Global Projected Drug Market Size for Select Indications



(1) By 2032 per Schizophrenia Market by Market Research Future 2024. (2) By 2028 per Bipolar Disorder Market by Skyquest Report 2022. (3) By 2032 per Major Depressive Disorder Market by Future Market Insights 2022. (4) By 2032 per ADHD market by Polaris Market Research 2023. (5) By 2032 per Pulmonary Arterial Hypertension (PAH) by Precedence Research 2023. (6) By 2031 per Idiopathic Pulmonary Fibrosis (IPF) by SkyQuest 2024. (7) By 2032 per Psoriasis Market by Precedence Research 2023. (8) By 2028 per Anxiety and Depression market, Report Linker 2023. (9) By 2030 per Morgan Stanley Research 2023

BD, a medical illness with substantial morbidity and mortality, involves episodic, recurrent mania or hypomania, and major depression. An article published in 2018 in the journal Therapeutic Advances in Psychopharmacology estimates that the global prevalence of bipolar spectrum disorders is approximately 2.4%, with approximately 0.6% for bipolar I and approximately 0.4% for bipolar II. The same journal article indicates prevalence of bipolar I in the U.S. has been found to be 1%, slightly higher than in other countries. In recent years, the general public awareness of the symptoms and treatment of BD is on the rise. Typically, the treatment for BD is for a lifetime. Antipsychotic drugs are the standard of care for patients with BD. According to a 2022 article from SkyQuest, the estimated global drugs market size for BD treatment is estimated to reach approximately $6.1 billion by the year 2028 (Figure 13).

MDD is a common, chronic, recurrent, and debilitating psychiatric condition, leading to significant impairments in personal functional capacities. MDD is one of the most common mental disorders in the United States. NIMH has estimated the prevalence of MDD among U.S. adults aged 18 or older at 17.3 million in 2017. NIMH also indicated the prevalence was higher among females (8.7%) compared to males (5.3%). Antipsychotic drugs are standard of care either as a monotherapy or as an adjuvant treatment for patients with MDD. According to a 2022 report from Future Market Insights, the estimated global drugs market size for the treatment of MDD is estimated to reach approximately $14.9 billion by the year 2032 (Figure 13).

ADHD is a lifespan neurodevelopmental disorder, which typically manifest early in development, characterized by severe difficulties maintaining attention, coupled with impulsivity and hyperactivity (American Psychiatric Association, 2013). Other related secondary symptoms of ADHD may be social, emotional, and learning impairments, and comorbidity with psychiatric disorders such as disruptive behavioral disorders, depression and anxiety disorders is relatively high. The ADHD features are displayed in a persistent pattern that is pervasive across multiple settings and causes substantial functional impairment of personal, social, academic, or occupational functioning. An article published in Lancet 2020 reported worldwide estimated prevalence of ADHD is 5.29%. According to a 2023 report from Polaris Market Research, the estimated global drugs market size for the treatment of ADHD is estimated to reach approximately $30.5 billion by the year 2032.

Respiratory Diseases Pulmonary Arterial Hypertension (PAH) and Idiopathic pulmonary Fibrosis (IPF)

PAH and IPF are serious fatal lung diseases. Currently, there is no cure for PAH and IPF diseases. PAH is a progressive, debilitating condition characterized by pulmonary vascular resistance leading to right ventricular failure and death. According to an article published in 2016 in the journal The Lancet Respiratory Medicine, the global prevalence of PAH is estimated at 6.6 – 26.0 cases per million with 1.1 – 7.6 incidences per million adults per year. The same article indicates PAH is frequently diagnosed in older patients, particularly those 65 years and older. As presented in 2020, NORD estimates PAH occurs 3 – 5 times more frequently in females than in males, and it tends to affect females between the ages of 30 and 60. Pursuant to a study published in 2012, post-diagnosis of PAH, survival rates are approximately 1 year in 85%, 3 years in 68%, and 5 years in 57% of patients, respectively (Benza RL et al, CHEST 2012, 142(2):448-456). We believe the PAH treatment market may exhibit growth as drivers accountable for the potential market growth include a globally growing older population coupled with causative diseases including interstitial lung diseases (ILD), human immunodeficiency virus (HIV) infection, connective tissue disorders, chronic liver diseases, sedentary lifestyle and other idiopathic conditions. The presence of favorable government support in the U.S. such as Orphan Drug Act (ODA) 1983 and the Rare Disease Act (RDA) of 2002 to facilitate the development of orphan drugs with benefits including tax incentives (reduced taxes/tax credits equal to half of the development costs), clinical research subsidies, and improved patent protection and marketing rights. According to a 2023 report from Precedence Research, the estimated global drugs market size for the treatment of PAH is projected to reach $12.1 billion by 2032 (Figure 13).

IPF is a chronic, progressive, and fatal lung disease. In 2019, Medscape reported the worldwide prevalence of IPF is estimated at 20 cases per 100,000 persons for males and 13 cases per 100,000 persons for females. Medscape also reported that in the U.S., the prevalence among individuals aged 50 years or older ranges from 27.9 to 63 cases per 100,000. Medscape also reported, for patients suffering from IPF, the estimated mean survival is 2 – 5 years from the time of diagnosis and that mortality rates are estimated at 64.3 deaths per million in men and 58.4 deaths per million in women. IPF involves chronic inflammation and progressive fibrosis of the alveoli. This pathology leads to destroyed lung architecture, reduced lung capacity, impaired oxygenation, and a decline in lung function. Treatment involves the FDA approved drugs nintedanib (Ofev), and pirfenidone (Esbriet), lung transplantation and palliative care. According to a 2024 report from SkyQuest, the estimated global drugs market size for IPF is anticipated to reach approximately $6.4 billion by 2031 (Figure 13).

Competition

The pharmaceutical industry is highly competitive and characterized by rapidly evolving technology and intense research and development efforts. We expect to compete with companies, including major international pharmaceutical companies, that have substantially greater financial, research and development, and marketing and sales capabilities, and have substantially greater experience in undertaking preclinical and clinical testing of products, obtaining regulatory approvals, and marketing and selling pharmaceutical products. We will face competition based on, among other things, product efficacy and safety, the timing and scope of regulatory approvals, product ease of use, and price.

At the highest level, our potential competitors are any company developing treatments for schizophrenia, PAH, IPF, BD, MDD, ADHD, BPSD, and PDP.

There are numerous therapies currently used to treat schizophrenia patients, including olanzapine, risperidone, quetiapine, and aripiprazole. Such products are also often used for the treatment of comorbid neuropsychiatric disorders, including BD, MDD, ADHD, BPSD, and PDP. While these offer some clinical benefit, they are associated with adverse side effects, which include neuroleptic side effects (e.g. EPS, akathisia), metabolic side effects (e.g. weight gain, obesity, type 2 diabetes, dyslipidemia) and endocrine side effects (e.g. hypothyroidism, prolactin increase leading to sexual dysfunction). Thus, we believe there is an unmet medical need for safe and effective drugs for the treatment of schizophrenia, and related comorbid neuropsychiatric disorders, that could potentially address the totality of the disorders and help patients function and feel better, with minimal side effects.

Additionally, there are numerous therapies currently used to treat PAH and IPF patients, including sildenafil, bosentan and treprostinil for PAH and nintedanib and pirfenidone for IPF. While these offer some clinical benefit, they are associated with treating the symptoms of such diseases, and not the underlying structural modification that causes the disease. Thus, we believe there is an unmet medical need for safe and effective drugs for the treatment of PAH and IPF that could potentially address the underlying cause for the disease while also treating known comorbid mental illness to potentially improve quality of life.

Sales and Marketing

We currently have no sales and marketing personnel. As a late-stage pharmaceutical company, we currently have no customers. We intend to develop domestic and international marketing, commercial operation, distribution, market access and reimbursement capabilities, or collaborate with third parties that have such infrastructure, in connection with the potential for FDA approval for brilaroxazine (RP5063) and RP1208.

Manufacturing and Supply

We have developed and validated a good manufacturing practice ("GMP"), process to manufacture the active pharmaceutical ingredient ("API") for our brilaroxazine (RP5063) drug candidate through contract manufacturers. We have an API contract manufacturer to produce bulk batches under GMP for our anticipated clinical studies and anticipate entering into agreements to produce sufficient API required prior to submitting a New Drug Application ("NDA") filing with the FDA. We do not own or operate manufacturing facilities for the production of brilaroxazine. We expect to depend on third-party suppliers and manufacturing organizations for all of our clinical trial quantities of raw materials and drug substance. We believe there are readily available supplies of all raw materials necessary for the manufacture of brilaroxazine and RP1208.

Employees

We have fourteen full-time employees, and utilize consultants, a contract research organization ("CRO") and third parties to perform our pre-clinical studies, clinical studies, manufacturing, regulatory, administrative, and financial functions. We believe our relations with our employees are good. We anticipate that the number of people we employ may grow significantly as we continue to develop our current products or if we develop new product candidates in the future.

Intellectual Property

We strive to protect our intellectual property through a combination of patent, copyright, trademark and trade secrets laws, as well as through confidentiality provisions in our contracts.

We strive to protect our intellectual property that we believe is important to our business, including our proprietary technology platform, our product candidates, and our processes. We seek patent protection in the U.S. and internationally for our products, their methods of use and processes of manufacture, and any other technology to which we have rights, where available and when appropriate. We also rely on trade secrets that may be important to the development of our business.

We also plan to seek trademark protection in the U.S. and outside of the U.S. where available and when appropriate. We intend to use these registered marks in connection with our pharmaceutical research and development as well as our product candidates.

We are the sole owner of a patent portfolio that includes issued patents and pending patent applications covering compositions of matter and methods of use of our product candidates RP5063 (brilaroxazine) and RP1208, as well as related compounds. As of March 27, 2024 our portfolio of intellectual property consists of 63 granted patents and 10 pending patent applications in the United States and in 23 foreign countries.

Brilaroxazine is our first intended commercial product. The original brilaroxazine patents include composition of matter, and methods of use in treating acute mania, autism, BD, depression, psychosis, and schizophrenia. One brilaroxazine original patent (U.S. Patent No. 8,188,076) and its 7 divisional/continuation patents have been granted in US. The original brilaroxazine patents have also been granted in the following foreign countries: Australia, Brazil, Canada, Germany, Spain, France, Great Britain, Hong Kong, Israel, India, Italy, Japan, S. Korea, Liechtenstein, Mexico, Russia, Slovakia, and Thailand; and pending in Columbia. We believe that our patent portfolio provides good protection of brilaroxazine. All of the US and foreign original brilaroxazine granted patents and pending patent applications will expire or are expected to expire in 2030, if a patent term extension is not obtained. If and when brilaroxazine receives regulatory approval, we intend to apply for patent term extensions on patents covering brilaroxazine in any jurisdiction where patent term extension is available. For example, the expiration date of the first US original brilaroxazine may be extendable up to 2035.

We also own additional brilaroxazine granted patents and pending patent applications for additional indications such as attention hyperactivity disorder (U.S. Patent No. 9,907,803, which will expire in 2036), pulmonary arterial hypertension (U.S. Patent No. 10,441,590, Japanese Patent No. 6787926, Chinese Patent No. CN107206007B, Hong Kong Patent No. 1244448) and a pending application in Europe; all of which will expire or are expected to expire in 2036), and pulmonary fibrosis (Japanese Patent No. 7343910, and pending applications in Brazil, China, Europe, Hong Kong, and US, which are expected to expire in 2038).

We further own three US patents (U.S. Patent Nos. 8,207,163; 8,247,420; 8,575,185; all of which will expire in 2030) directed to composition and use of compounds related to brilaroxazine.

We also have two US provisional applications pending, directed to a new formulation of brilaroxazine and a method of using brilaroxazine for treating a new indication.

We intend to continue to file patent applications to cover additional patentable aspects of brilaroxazine including new indications and to endeavor to exclude competitors from entering the field.

RP1208 may be our second intended commercial product. The RP1208 patents include composition of matter, and methods of use in treating depression and obesity. Three RP1208 patents have been granted in the US. RP1208 patents have also been granted in the following foreign countries: Australia, Canada, China, Columbia, Germany, Spain, France, Great Britain, Hong Kong, India, Italy, Mexico, Malaysia, Philippines, Russia, Singapore, and South Africa; and is pending in Thailand. We believe that our patent portfolio provides good protection of RP1208. The first RP1208 US patents will expire in 2033 and may be extendable up to 2038. The other two RP1208 continuation US patents will expire in 2032. All foreign RP1208 granted patents and pending patent applications will expire or are expected to expire in 2032. If and when RP1208 receives regulatory approval, we intend to apply for patent term extensions on patents covering RP1208 in any jurisdiction where patent term extension is available.

We also own two families of US patents directed to related compounds of RP1208 covering composition and use. The first family consists of US Patent No. 7,989,500 and its 5 granted continuation patents, which will expire in 2027 or 2028. The second family consists of US Patent No. 8,604,244 and its 2 granted continuation patents, which will expire in 2031.

In addition to patents, we also rely upon proprietary know-how (including trade secrets) to protect our technology and maintain and develop our competitive position. In some situations, maintaining information such as a trade secret may be more appropriate to protect the type of technology than filing a patent application. We seek to protect our confidential and proprietary information in part by confidentiality agreements, and it is our policy generally to have our employees, consultants, scientific advisors, outside scientific collaborators, sponsored researchers, investors, prospective investors and contractors execute such agreements upon the commencement of a relationship with us.

Our success will depend on 1) the ability to obtain and maintain patent and other proprietary rights in commercially important technology, inventions and know-how related to our business, 2) the validity and enforceability of our patents, 3) the continued confidentiality of our trade secrets, and 4) our ability to operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position.

We cannot be certain that patents will be granted with respect to any of our pending patent applications, nor can we be certain that any of our existing patents will be successful in protecting our technology. For this and more comprehensive risks related to our intellectual property, please see “Risk Factors — Risks Related to our Intellectual Property.”

Regulatory Matters

The FDA and other federal, state, local and foreign regulatory agencies impose substantial requirements upon the clinical development, approval, labeling, manufacture, marketing and distribution of drug products. These agencies regulate, among other things, research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, advertising and promotion of our product candidates. Products that we may develop or acquire in the future must be approved by the FDA before they may be legally marketed in the United States. The regulatory approval process is generally lengthy and expensive, with no guarantee of a positive result. Moreover, failure to comply with applicable requirements by the FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, injunctive relief including partial or total suspension of production, or withdrawal of a product from the market.

The FDA regulates, among other things, the research, manufacture, promotion and distribution of drugs in the U.S. under the Federal Food, Drug, and Cosmetic Act ("FDCA") and other statutes and implementing regulations. The process required by the FDA before prescription drug product candidates may be marketed in the U.S. generally involves the following:

- completion of extensive nonclinical laboratory tests, animal studies and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice regulations;

- submission to the FDA of an Investigational New Drug application ("IND"), which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials in accordance with the FDA's regulations, including Good Clinical Practices, to establish the safety and efficacy of the product candidate for each proposed indication;

- showing that a contemplated drug product can be formulated, tested and manufactured in compliance with quality control rules;

- submission to the FDA of an NDA for drug products, or a Biologics License Application ("BLA"), for biologic products;

- satisfactory completion of a preapproval inspection by the FDA of the manufacturing facilities at which the product is produced to assess compliance with current GMP ("cGMP") regulations; and

- the FDA's review and approval of the NDA or BLA prior to any commercial marketing, sale or shipment of the drug.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Nonclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals and other animal studies. The results of nonclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. Nonclinical testing often continues after an IND is submitted. The IND also includes one or more protocols for the initial clinical trial or trials and an investigator's brochure. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to the proposed clinical trials as outlined in the IND and places the clinical trial on a clinical hold. In such cases, the IND sponsor and the FDA must resolve any outstanding concerns or questions before any clinical trials can begin. Clinical trial holds also may be imposed at any time before or during studies due to safety concerns or non-compliance with regulatory requirements. An independent Institutional Review Board ("IRB"), at each of the clinical centers proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the consent form signed by the trial participants and must monitor the study until completed.

Clinical Trials

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified medical investigators according to approved protocols that detail the objectives of the study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor participant safety. Each protocol for a U.S. study is submitted to the FDA as part of the IND.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap, or be combined.

- Phase 1 clinical trials typically involve the initial introduction of the product candidate into healthy human volunteers. In Phase 1 clinical trials, the product candidate is typically tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.

- Phase 2 clinical trials are generally conducted in a limited patient population to gather evidence about the efficacy of the product candidate for specific, targeted indications; to determine dosage tolerance and optimal dosage; and to identify possible adverse effects and safety risks. Phase 2 clinical trials, in particular Phase 2b trials, can be undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites.

- Phase 3 clinical trials are undertaken to evaluate clinical efficacy and to test for safety in an expanded patient population at geographically dispersed clinical trial sites. The size of Phase 3 clinical trials depends upon clinical and statistical considerations for the product candidate and disease. Phase 3 clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

Clinical testing must satisfy the extensive regulations of the FDA. Reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted for serious and unexpected adverse events. Success in early-stage clinical trials does not assure success in later-stage clinical trials. We, or the FDA or an IRB, may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk.

Chemistry, Manufacturing and Controls

Concurrent with clinical trials, companies typically complete additional animal and laboratory studies, develop additional information about the chemistry and physical characteristics of the drug, and finalize a process for manufacturing the product in commercial quantities in accordance with FDA's current Good Manufacturing Practices ("cGMP") requirements. The manufacturing process must consistently produce quality batches of the drug, and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life.

New Drug Applications

Assuming successful completion of the required clinical trials, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA (or BLA, in the case of a biologic product). An NDA or BLA also must contain extensive manufacturing information, as well as proposed labeling for the finished product. An NDA or BLA applicant must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP. The manufacturing process must be capable of consistently producing quality product within specifications approved by the FDA. The manufacturer must develop methods for testing the quality, purity and potency of the final product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life. Prior to approval, the FDA will conduct an inspection of the manufacturing facilities to assess compliance with cGMP.

The FDA reviews all NDAs and BLAs submitted before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA or BLA must be resubmitted with the additional information and is subject to review before the FDA accepts it for filing. After an application is filed, the FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers them carefully when making decisions. The FDA may deny approval of an NDA or BLA if the applicable regulatory criteria are not satisfied. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA may issue a complete response letter, which may require additional clinical or other data or impose other conditions that must be met in order to secure final approval of the NDA or BLA. If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require us to conduct Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA or BLA approval, and may require surveillance programs to monitor the safety of approved products which have been commercialized. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety or efficacy questions are raised after the product reaches the market.

Section 505(b) NDAs

There are two types of NDAs: the Section 505(b)(1) NDA, or full NDA, and the Section 505(b)(2) NDA. Our current plans call for us to pursue only full NDAs. A full NDA is submitted under Section 505(b)(1) of the FDCA, and must contain full reports of investigations conducted by the applicant to demonstrate the safety and effectiveness of the drug.

Marketing Exclusivity

The FDCA provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity ("NCE"), meaning that the FDA has not previously approved any other drug containing the same active moiety. This exclusivity prohibits the submission of a Section 505(b)(2) NDA or an ANDA for any drug product containing the active ingredient during the five-year exclusivity period. However, submission of a Section 505(b)(2) NDA or an ANDA that certifies that a listed patent is invalid, unenforceable, or will not be infringed, as discussed above, is permitted after four years, but if a patent infringement lawsuit is brought within 45 days after such certification, FDA approval of a Section 505(b)(2) NDA or ANDA may automatically be stayed for as long as 7½ years after the NCE approval date. The FDCA also provides three years of marketing exclusivity for the approval of new and supplemental NDAs for product changes, including, among other things, new indications, dosage forms, routes of administration or strengths of an existing drug, or for a new use, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by FDA to be essential to the approval of the application. Five-year and three-year exclusivity will not delay the submission or approval of another full NDA; however, as discussed above, an applicant submitting an ANDA or full NDA under Section 505(b)(1) would be required to conduct or obtain a right of reference to all of the nonclinical and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA or NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product marketing exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same use or indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA or NDA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if the second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

The FDA has four programs in place intended to facilitate and expedite development and review of new drugs and biologics intended to address unmet medical needs in the treatment of serious or life-threatening conditions. These are Fast Track Designation, Breakthrough Therapy Designation, Accelerated Approval Program, and Priority Review Designation.

The Fast Track program is intended to expedite or facilitate the process for reviewing a new product if it is intended for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. Fast Track Designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

A product can receive Breakthrough Therapy Designation if it is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A Breakthrough Therapy Designation conveys all of the features of Fast Track Designation in addition to more intensive FDA guidance on an efficient development program, organizational commitment involving senior managers, and eligibility for priority review. Specifically, the FDA intends to expedite the development and review of a Breakthrough Therapy by, where appropriate, intensively involving senior managers and experienced review staff in a proactive collaborative, cross-disciplinary review. Where appropriate, the FDA also intends to assign a cross-disciplinary project lead for the review team to facilitate an efficient review of the development program. The FDA notes that a compressed drug development program still must generate adequate data to demonstrate that the drug or biologic meets the statutory standard for approval. Omitting components of the development program that are necessary for such a determination can significantly delay, or even preclude, marketing approval.

Breakthrough Therapy Designation indicates that preliminary clinical evidence demonstrates the drug may have substantial improvement on one or more clinically significant endpoints over available therapy. Breakthrough Therapy Designation intensifies FDA involvement to ensure an efficient drug development program and is an organizational commitment from the FDA to involve its senior managers. A sponsor receiving Breakthrough Therapy Designation has up to six months after receiving the Breakthrough Therapy Designation to request an Initial Comprehensive Multidisciplinary meeting to discuss the drug development program. This initial meeting is a Type B meeting, used to discuss the overarching, high-level plan for drug development. These discussions include topics such as planned clinical trials and endpoints, any resizing or adaptations to the trials, plans for expediting the manufacturing development strategy and studies that potentially could be completed after approval. When Breakthrough Therapy Designation has been granted, the FDA is encouraged to meet regularly with the sponsor and subsequent meetings are considered Type B meetings and are established based on the needs of the program.

The FDA may grant accelerated approval under its Accelerated Approval Program to a product candidate for a serious or life-threatening condition upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Accelerated approval is contingent on a sponsor's agreement to conduct at least one adequate and well-controlled additional post-approval trial to verify and describe the product's clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track Designation, Breakthrough Therapy Designation, RMAT, and Accelerated Approval do not change the standards for approval but may expedite the development process. Additionally, Fast Track Designation or Breakthrough Therapy Designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process, including considering any new drug or biologic approvals that later the unmet medical need.

An application for a product candidate may be eligible to obtain Priority Review Designation if it is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. A Priority Review Designation means FDA's goal is to take action on the marketing application within six months (compared to ten months under standard review) of the 60-day filing date. Priority Review Designation does not change the standards for approval but may expedite the review process.

Other Regulatory Requirements

Maintaining substantial compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Drug manufacturers are required to register their establishments with the FDA and certain state agencies, and after approval, the FDA and these state agencies conduct periodic unannounced inspections to ensure continued compliance with ongoing regulatory requirements, including current good manufacturing practice regulations (cGMPs). In addition, after approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. The FDA may require post-approval testing and surveillance programs to monitor safety and the effectiveness of approved products that have been commercialized. Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including:

- compliance with cGMPs;
- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- reporting on advertisements and promotional labeling;
- drug sampling and distribution requirements; and
- complying with electronic record and signature requirements.

In addition, the FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. There are numerous regulations and policies that govern various means for disseminating information to health-care professionals as well as consumers, including to industry sponsored scientific and educational activities, information provided to the media and information provided over the Internet. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label.

The FDA has very broad enforcement authority and the failure to comply with applicable regulatory requirements can result in administrative or judicial sanctions being imposed on us or on the manufacturers and distributors of our approved products, including warning letters, refusals of government contracts, clinical holds, civil penalties, injunctions, restitution and disgorgement of profits, recall or seizure of products, total or partial suspension of production or distribution, withdrawal of approvals, refusal to approve pending applications, and criminal prosecution resulting in fines and incarceration. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. In addition, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Coverage and Reimbursement

Sales of our product candidates, if approved, will depend, in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage or reducing reimbursements for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any drug candidates that we develop will be made on a payor-by-payor basis. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician usage of our product candidates, once approved, and have a material adverse effect on our sales, results of operations and financial condition.

Other Healthcare Laws

Because of our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors, we will also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we will conduct our business, including our clinical research, proposed sales, marketing and educational programs. Failure to comply with these laws, where applicable, can result in the imposition of significant civil penalties, criminal penalties, or both. The U.S. laws that may affect our ability to operate, among others, include: the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; certain state laws governing the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; the federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs; federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent; federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that our products are sold in a foreign country, we may be subject to similar foreign laws.

The Impact of New Legislation and Amendments to Existing Laws

The FDCA is subject to routine legislative amendments with a broad range of downstream effects. In addition to new legislation, such as the FDA Reauthorization Act of 2017 or the FDASIA in 2012, Congress introduces amendments to reauthorize drug user fees and address emerging concerns every five years. We cannot predict the impact of these new legislative acts and their implementing regulations on our business. The programs established or to be established under the legislation may have adverse effects upon us, including increased regulation of our industry. Compliance with such regulation may increase our costs and limit our ability to pursue business opportunities. In addition, the FDA's regulations, policies and guidance are often revised or reinterpreted by the agency or the courts in ways that may significantly affect our business and products.

We expect that additional federal and state, as well as foreign, healthcare reform measures will be adopted in the future, any of which could result in reduced demand for our products or additional pricing pressure.

Where You Can Find More Information

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission, or the SEC. Our SEC filings are available to the public over the internet at the SEC's website at *http://www.sec.gov*. Our website is located at https://revivapharma.com/. On our website, investors can obtain, free of charge, a copy of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, our Code of Business Conduct and Ethics, including disclosure related to any amendments or waivers thereto, other reports and any amendments thereto filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act of 1934, as amended, as soon as reasonably practicable after we file such material electronically with, or furnish it to, the SEC. Our website and the information contained on or connected to that site are not incorporated into this Annual Report on Form 10-K. We will provide, without charge, to each person upon written request of such person, a copy of this Annual Report on Form 10-K, including the financial statements and financial statement schedules included herein. You should direct requests for those documents to:

Reviva Pharmaceuticals Holdings, Inc.
10080 N. Wolfe Road, Suite SW3-200
Cupertino, CA 95014
Attn: Investor Relations
Email: info.rp@revivapharma.com

Item 1A. RISK FACTORS

An investment in our common stock is speculative and illiquid and involves a high degree of risk including the risk of a loss of your entire investment. You should carefully consider the risks and uncertainties described below and the other information contained in this report and our other reports filed with the SEC. The risks set forth below are not the only ones facing us. Additional risks and uncertainties may exist that could also adversely affect our business, operations and financial condition. If any of the following risks actually materialize, our business, financial condition and/or operations could suffer. In such event, the value of our common stock could decline, and you could lose all or a substantial portion of the money that you pay for our common stock.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties. The following summarizes key risks and uncertainties that could materially adversely affect us. You should read this summary together with the more detailed risk factors contained below.

- We have never generated any product revenues;
- we expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability;
- our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern;
- we are heavily dependent on the success of brilaroxazine, our only advanced product candidate, which is still under clinical development, and if brilaroxazine does not receive regulatory approval or is not successfully commercialized, our business will be harmed;
- we face risks related to health epidemics and outbreaks, including any future health crises, pandemics or other events, which could adversely impact our business, including our clinical trials;
- raising additional funds by issuing securities may cause dilution to existing stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights;
- we have identified material weaknesses in our internal control over financial reporting as of December 31, 2024. If we fail to maintain an effective system of internal control, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Common Stock and listed Warrants;
- if the interpretations, estimates or judgments we use to prepare our financial statements prove to be incorrect, we may be required to restate our financial results, which could have a number of material adverse effects on us;
- clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome;
- we face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively;

- we do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of brilaroxazine, RP1208 and any future product candidate;
- we rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business;
- if we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets;
- our officers, directors, and principal stockholders exercise significant control over our Company, and will control our Company for the foreseeable future, including the outcome of matters requiring stockholder approval;
- if we fail to maintain compliance with the requirements of The Nasdaq Capital Market for continued listing, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted;
- certain of our warrants are accounted for as liabilities and the changes in value of such warrants could have a material effect on our financial results; and
- we do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, any gains from an investment in our common stock will likely depend on appreciation in the price of our common stock.

Risks Related to Our Business, Financial Position and Capital Requirements

We have never generated any product revenues.

We are a late-stage pharmaceutical company. Although we were formed in May 2006, to date, we have not generated any product revenues from our product candidates currently in development. We have not yet demonstrated an ability to successfully complete a full pre-marketing development program, obtain marketing approval, manufacture a commercial scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

Consequently, we have no meaningful operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of our product candidates, brilaroxazine for the treatment of schizophrenia, respiratory/pulmonary diseases such as Pulmonary Arterial Hypertension, or PAH, and Idiopathic Pulmonary Fibrosis, or IPF, and for other neuropsychiatric diseases, such as bipolar disorder, or BD, major depressive disorder, or MDD, Alzheimer's psychosis/agitation, or AD, Parkinson's psychosis, or PD, and attention deficit hyperactivity disorder, or ADHD/ADD, and RP1208 for the treatment of depression and obesity, and obtain the necessary regulatory approvals for their commercialization. We have never been profitable, have no products approved for commercial sale and to date have not generated any revenue from product sales.

Even if we receive regulatory approval for the commercialization of brilaroxazine, we do not know when this product candidate will generate revenue, if at all. RP1208 is in pre-clinical development. Our ability to generate product revenue depends on a number of factors, including our ability to:

- successfully develop, complete pre-clinical and clinical trials and obtain regulatory approval for the marketing of our product candidates;
- set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors;
- establish sales, marketing and distribution systems for our product candidates;
- add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts and operations;
- initiate and continue relationships with third-party manufacturers and have commercial quantities of our product candidates manufactured at acceptable cost levels;
- attract and retain an experienced management and advisory team;
- achieve broad market acceptance of our products in the medical community and with third-party payors and consumers;
- launch commercial sales of our products, whether alone or in collaboration with others; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the FDA, and comparable non-U.S. regulatory authorities, to perform studies or clinical trials in addition to those that we currently anticipate. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of these products. If we cannot successfully execute any one of the foregoing, our business, prospects and results of operations may be adversely affected.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have never generated any revenues and cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale and we may never generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and increasing losses through the projected commercialization of brilaroxazine and RP1208. For the year ended December 31, 2024, we reported a loss of $29.9 million and a negative cash flow from operations of $33.5 million. We had an accumulated deficit of $164.3 million and had cash and cash equivalents of $13.5 million as of December 31, 2024.

Brilaroxazine has not been approved for marketing in the United States and may never receive such approval. Although RP1208 may be in IND enabling studies for depression and may be in animal efficacy studies for obesity within a short time frame following the receipt of adequate additional financing, it is not currently in an IND-enabling study or animal efficacy study, respectively, and may never meet the requirements for filing an IND. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to produce revenue and achieve profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals, and have our product candidates manufactured and successfully marketed. We cannot assure you that we will be profitable even if we successfully commercializes our product candidates. If we do not successfully obtain regulatory approval to market our product candidates, our revenues will be dependent, in part, upon, among other things, the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, the accepted price for our product candidates and whether we own the commercial rights for that territory. If the indication approved by regulatory authorities is narrower than we expects, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the timing of our clinical results and our ability to raise capital and continue operations.

We expect our research and development expenses to be significant in connection with the following ongoing and planned research:

- further studies in connection with our clinical development plan for brilaroxazine for schizophrenia, including completion of our ongoing 1-year open label extension (OLE) trial evaluating long-term safety and tolerability, and our planned registrational RECOVER-2 Trial;
- Phase 2 studies for the treatment of PAH, IPF, BD, MDD, AD, PD, ADHD/ADD;
- pre-clinical studies and clinical studies for RP1208 for the treatment of depression and obesity.

Further, we will require additional capital to proceed with the planned research described above. See "Risks Related to Our Business, Financial Position and Capital Requirements — We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of brilaroxazine and RP1208."

In addition, if we obtain regulatory approval for brilaroxazine, we expect to incur increased sales and marketing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital.

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

We have recognized recurring losses, and as of December 31, 2024, had an accumulated deficit of $164.3 million. We anticipate operating losses to continue for the foreseeable future due to, among other things expenses related to ongoing activities to research, develop and commercialize our product candidates. We expect the cash and cash equivalents of $13.5 million at December 31, 2024 to be insufficient to meet our operating and capital requirements at least 12 months from the filing of this Annual Report on Form 10-K. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative and research and development activities are forward-looking statements and involve risks and uncertainties. The financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

As further described below, our ability to continue as a going concern is dependent on our ability to raise additional working capital through public or private equity or debt financings or other sources, which may include collaborations with third parties as well as disciplined cash spending. Should we be unable to raise sufficient additional capital, we may be required to undertake cost-cutting measures including delaying or discontinuing certain clinical activities. The sale of equity and convertible debt securities may result in dilution to our stockholders and certain of those securities may have rights senior to those of our common stock. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights.

The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our planned clinical trials or research and development programs or make changes to our operating plan, or curtail or cease operations These factors among others create a substantial doubt about our ability to continue as a going concern.

We are heavily dependent on the success of brilaroxazine, our only advanced product candidate, which is still under clinical development, and if brilaroxazine does not receive regulatory approval or is not successfully commercialized, our business will be harmed.

We currently have no products that are approved for commercial sale and may never be able to develop marketable drug products. We expect that a substantial portion of our efforts and expenditures in the foreseeable future will be devoted to brilaroxazine. Our only other product candidate is RP1208, which is in the pre-clinical phase. We do not expect to allocate a significant portion of our efforts or resources to the clinical trials or development of this product candidate in the foreseeable future. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of brilaroxazine. We cannot be certain that brilaroxazine will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market brilaroxazine in the United States until we receive approval of a new drug application, or NDA, from the FDA, or in any foreign countries until we receives the requisite approval from such countries. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining approval of an NDA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of brilaroxazine and our other product candidates for many reasons, including:

- We may not be able to demonstrate that brilaroxazine is safe and effective as a treatment for our targeted indications to the FDA's satisfaction;
- the FDA may require additional Phase 3 trials of brilaroxazine in schizophrenia, which would increase our costs and prolong its development;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA may not find the data from preclinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of brilaroxazine outweigh its safety risks;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials or may require that we conduct additional studies;
- the FDA may not accept data generated at our clinical trial sites;
- if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a risk evaluation and mitigation strategy, or REMS, as a condition of approval;
- the FDA may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA may change its approval policies or adopt new regulations.

We face risks related to health epidemics and outbreaks, including any future health crises, pandemics or other events, which could adversely impact our business, including our clinical trials.

Disease outbreaks, epidemics and pandemics, in regions where we have concentrations of clinical trial sites and other business operations, could adversely affect our business, including by causing significant disruptions in our operations and/or in the operations of manufacturers and CROs upon whom we rely. Disease outbreaks, epidemics and pandemics may have negative impacts on our ability to initiate new clinical trial sites, enroll new patients and maintain existing patients who are participating in clinical trials, which may result in increased clinical trial costs, longer timelines and delays in our ability to obtain regulatory approvals of our product candidates, if at all. For example, patient enrollment and recruitment could be delayed due to local clinical trial site protocols designed to protect staff and patients from certain outbreaks, which could delay the expected timelines for data readouts of our preclinical studies and clinical trials. Additionally, general supply chain issues may be exacerbated during disease outbreaks, epidemics or pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all. Moreover, the extent to which disease outbreaks, epidemics and pandemics may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence. New health epidemics or pandemics may emerge that result in similar or more severe disruptions to our business. A future disease outbreak, epidemic or pandemic adversely affects our business, financial condition, results of operations and growth prospects.

As a result of the COVID-19 pandemic, we previously experienced, and in the event of any future outbreaks, epidemics or health crises, may experience disruptions that could severely impact our business and clinical trials. The effects of any health crises in the future, such as future resurgence or new strains or outbreaks, and the potential effects on our business and operations are uncertain. The impacts of potential future health crises could pose the risk that we or our employees, suppliers, future customers in the event of product approval, and others may be restricted or prevented from conducting business activities for indefinite or intermittent periods of time, including as a result of employee health and safety concerns, shutdowns, shelter in place orders, travel restrictions and other actions and restrictions that may be prudent or required by governmental authorities. This could disrupt our ability to operate our business, including producing drug product and administering our preclinical and clinical studies. In addition, fluctuations in demand and other implications associated with the COVID-19 pandemic previously resulted in, and similar crises could in the future result in, certain supply chain constraints and challenges in the broader markets and economy generally, which could impact our business and supply sources.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of brilaroxazine or RP1208.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for, and commercialize brilaroxazine and RP1208. We will require additional capital to complete the development and potential commercialization of brilaroxazine for the treatment of schizophrenia and to continue the development of brilaroxazine for PAH, IPF, BD, MDD, AD, PD, ADHD/ADD and other potential indications, and to continue the development of RP1208 for the treatment of depression and obesity. No assurance can be given that such additional capital will be available on terms acceptable to us, if at all. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our planned development programs or any future commercialization efforts. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. Because the length of time and activities associated with successful development of brilaroxazine and RP1208 is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our planned clinical trials for brilaroxazine and pre-clinical research for RP1208;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us with respect to brilaroxazine, RP1208 or any future product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for brilaroxazine, RP1208 or any future product candidates, in regions where we choose to commercialize our products on our own; and
- the initiation, progress, timing and results of our commercialization of brilaroxazine, RP1208 or any future product candidates, if approved for commercial sale.

We cannot be certain that such funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of brilaroxazine or RP1208 or potentially discontinue operations.

Raising additional funds by issuing securities may cause dilution to existing stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements in connection with any collaborations. We do not have any committed external source of funds. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect then-existing stockholders' interests. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our shares or make investments. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves, make changes to our operating plan, or curtail or cease operations.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2024, we had fourteen employees, and we are highly dependent on our management personnel, especially Laxminarayan Bhat, our Chief Executive Officer and Narayan Prabhu, our Chief Financial Officer. We expect to hire a significant number of additional employees for our managerial, clinical, scientific, operational, sales and marketing teams. We may have operational difficulties in connection with identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management has no prior experience in managing these growth activities and may need to divert a disproportionate amount of our attention away from our day-to-day activities and devote a substantial amount of time to such activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize brilaroxazine and RP1208 and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can discover and develop product candidates and our business will be limited.

Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If we seek to enter into strategic alliances for the development of brilaroxazine or RP1208 but fail to enter into and maintain successful strategic alliances, our development costs may increase and our ability to develop brilaroxazine or RP1208 may be significantly delayed.

We may seek to enter into strategic alliances or collaborative arrangements with pharmaceutical companies or other industry participants in order to advance our development of brilaroxazine or, in the future, RP1208 or other product candidates, and to reduce our costs of development. If we seek such alliances or collaborative arrangements, we may not be able to negotiate such alliances or collaborative arrangements on acceptable terms, if at all. We face significant competition from other biopharmaceutical companies for appropriate partners in such alliances or arrangements. Furthermore, if we are successful in entering strategic alliances or collaborative arrangements, we may not be able to maintain such alliances or arrangements for a sufficient amount of time to commercialize brilaroxazine, RP1208 or other product candidates, or such alliances or arrangements may not result in successful development of our products. If we seek suitable alliances or arrangements but then fail to create or to maintain these, we may have to limit the size or scope of, or delay, our development of brilaroxazine, RP1208 or other future product candidates. If we elect to fund our development or research programs on our own, we will have to increase our expenditures and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms. See "*Risks Related to Our Business, Financial Position and Capital Requirements — We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of brilaroxazine and RP1208.*"

To the extent we are able to enter into collaborative arrangements or strategic alliances, we will be exposed to risks related to those collaborations and alliances.

Biotechnology companies at our stage of development may become dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of drug candidates, particularly after the Phase 2 stage of clinical testing. If we elect to enter into collaborative arrangements or strategic alliances, these arrangements may place the development of brilaroxazine, RP1208 or other future product candidates outside our control, may require that we relinquish important rights or may otherwise be entered on terms unfavorable to us.

Dependence on collaborative arrangements or strategic alliances will subject us to a number of risks, including the risk that:

- We may not be able to control the amount and timing of resources that our collaborators may devote to brilaroxazine and RP1208;
- our collaborators may experience financial difficulties;
- we may be required to relinquish important rights, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete our obligations under any arrangement;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates.

Our business and operations would suffer in the event our computer systems and networks fail.

Our business depends on the proper functioning and availability of our computer systems and networks. Our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, threat actors, ransomware, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of brilaroxazine, RP1208 or any future product candidate could be delayed. Any successful cyber-security attack or other unauthorized attempt to access our systems also could result in negative publicity which could damage our reputation or brand with our patients, referral sources, payors or other third parties and could subject us to substantial penalties under HIPAA and other federal and state privacy laws, in addition to private litigation with those affected.

Computer system interruptions, cyber-attacks or security breaches could significantly disrupt our product development programs and our ability to operate our business.

Our computer systems, as well as those of various third parties on which we rely, may sustain damage from computer viruses, threat actors, ransomware, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any significant system failure, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any product candidate could be delayed.

Furthermore, federal, state and international laws and regulations, such as the European Union's General Data Protection Regulation, or the GDPR, which took effect in May 2018, and the California Consumer Protection Act, which took effect on January 1, 2020, can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail or if our privacy practices do not meet the requirements of such laws. Other states are considering similar laws that could impact our use of research data with respect to individuals in those states. There are extensive documentation obligations and transparency requirements, which may impose significant costs on us. In addition, our software systems include cloud-based applications that are hosted by third-party service providers with security and information technology systems subject to similar risks. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed, any of which could materially adversely affect our business, financial condition, results of operations and growth prospects.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of brilaroxazine and RP1208 in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize brilaroxazine, RP1208 or any future product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for brilaroxazine, RP1208 or any future product candidate, if approved for commercial sale; and
- loss of revenue.

Any product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for brilaroxazine or RP1208, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop.

We have identified material weaknesses in our internal control over financial reporting as of December 31, 2024. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Common Stock and listed Warrants.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our securities.

We have limited operating history and limited personnel in our finance and accounting functions, which may result in a lack of segregation of duties and we are at the relatively very early stages of establishing our systems of internal controls, and we may be unable to effectively maintain such systems. This would leave us without the ability to reliably assimilate and compile financial information and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on our internal controls over financial reporting.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are a non-accelerated filer under the U.S. securities laws, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

As more particularly described in this Annual Report on Form 10-K below in "Item 9A. Controls and Procedures." we have identified material weaknesses in our internal control over financial reporting as of December 31, 2024, including (i) an entity-level material weakness involving an ineffective control environment, including an insufficient number of personnel with an appropriate level of knowledge and experience to create the proper environment for effective internal control over financial reporting, and not maintaining the other components of the Committee of Sponsoring Organizations of the Treadway Commission framework, including appropriate risk assessment, control activities, information and communication, and certain monitoring activities components, and (ii) the entity-level material weaknesses contributed to other material weaknesses within our system of internal control over financial reporting, including (a) we did not design and maintain effective information technology (IT) general controls for certain information systems supporting our key financial reporting processes, and (b) we did not design and maintain effective process-level controls, which affects substantially all account balances and disclosures. These material weaknesses have a pervasive impact and consequently, impact control activities over all financial statement account balances, classes of transactions, and disclosure. We are committed to continuing to improve our internal control over financial reporting. As of the date hereof, we have commenced procedures to remediate the material weaknesses. We will continue to monitor the design and effectiveness of these procedures and controls and make any further changes we determine appropriate. However, these material weaknesses will not be considered remediated until the applicable remedial actions have been fully implemented and we have concluded that these controls are operating effectively for a sufficient period of time.

We have incurred significant expenses, including audit, legal, consulting and other professional fees, in connection with the ongoing remediation of material weaknesses in our internal control over financial reporting. We are implementing and will continue to implement additional processes utilizing existing resources and adding new resources as needed. To the extent these steps are not successful, we could be forced to incur additional time and expense. Our management's attention has also been diverted from the operation of our business in connection with the ongoing remediation of material weaknesses in our internal controls.

If the interpretations, estimates or judgments we use to prepare our financial statements prove to be incorrect, we may be required to restate our financial results, which could have a number of material adverse effects on us.

We are subject to complex securities laws and regulations and accounting principles and interpretations. The preparation of our financial statements requires us to interpret accounting principles and guidance and to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. We base our interpretations, estimates and judgments 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 the preparation of our financial statements. Generally accepted accounting principles presentation is subject to interpretation by the SEC, the Financial Accounting Standards Board and various other bodies formed to interpret and create appropriate accounting principles and guidance. If one of these bodies disagrees with our accounting recognition, measurement or disclosure or any of our accounting interpretations, estimates or assumptions, it may have a significant effect on our reported results and may retroactively affect previously reported results.

Specifically, prior to and in connection with the closing of our Business Combination, our predecessor company, Tenzing, issued public warrants to purchase 6,325,000 shares (the "Public Warrants") and liability classified private-placement warrants to purchase 556,313 shares (the "Private Warrants"). For a full description of the Public Warrants and the Private Warrants, refer to (i) the registration statement on Form S-4 (File No. 333-245057), filed in connection with the Business Combination, declared effective by the SEC on November 10, 2020 and (ii) our "Description of Securities" included as Exhibit 4.1 to this Annual Report on Form 10-K. Each of the Public Warrants and Private Warrants entitles the holder to purchase one share of our common stock at a price of $11.50 per share, subject to adjustment. We originally classified the Public Warrants and the Private Warrants as equity in our previously issued audited consolidated balance sheet as of December 31, 2020, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the year then ended, and the related notes (collectively, referred to as the "Financial Statements") included in our Annual Report on Form 10-K filed on March 22, 2021.

On April 12, 2021, the Staff of the Securities and Exchange Commission ("SEC Staff") released the Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies (the "Statement"). In the Statement, SEC Staff made the observation that certain contractual provisions included in many Special Purpose Acquisition Company warrant agreements may result in such warrants needing to be classified as a liability rather than as equity.

We have reviewed the Statement and the terms of our Public Warrants and Private Warrants with our third-party technical accounting advisor and our independent auditors and management has concluded that the Private Warrants should be reclassified as liabilities measured at fair value, which will result in non-cash gains or losses from changes in fair value reported each period in earnings.

However, no assurance can be given that additional guidance or new regulations or accounting principles and interpretations will not be released that would require us to reclassify the Public Warrants as liabilities measured at fair value, with changes in fair value reported each period in earnings and/or require a restatement of our Financial Statements with respect to treatment of the Public Warrants.

Any restatement of our financial results could, among other potential adverse effects:

- result in us incurring substantial costs;
- affect our ability to timely file our periodic reports until the restatement is completed;
- divert the attention of our management and employees from managing our business;
- result in material changes to our historical and future financial results;
- result in investors losing confidence in our operating results;
- subject us to securities class action litigation; and
- cause our stock price to decline.

Unfavorable global economic conditions and adverse developments with respect to financial institutions and associated liquidity risk could adversely affect our business, financial condition and stock price.

The global credit and financial markets are currently, and have from time to time experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates, uncertainty about legal and regulatory changes, including potential changes to tax laws, and new or increased tariffs and the potential for retaliatory tariffs and "trade wars" and consequential effects on the economy, and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability.

In 2023, the closures of Silicon Valley Bank ("SVB") and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation (the "FDIC") created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at SVB and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of market participants to access near-term working capital needs, and create additional market and economic uncertainty. Since the March 2023 failure and FDIC takeover of SVB and the inability of its customers to readily access their cash deposits, there has been a heightened risk and greater focus on the potential failures of other banks in the future. As of December 31, 2024, we maintained all of our cash with three financial institutions, including SVB, and certain of our cash balance with these financial institutions were in excess of the FDIC insurance limit. If these banks fail in the future, we may not be able to immediately (or ever) recover our cash in excess of the FDIC insured limits which would adversely impact our operating liquidity and could negatively impact our operations, results of operations and financial performance.

Although as described above federal regulators announced that the FDIC would complete its resolution of SVB in a manner that protects all depositors under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

Risks Related to Development, Regulatory Approval and Commercialization

Drug development is a very expensive, lengthy and uncertain process.

The process of taking a drug from discovery to approval generally takes many years, costs tens of millions of dollars or more and has a low probability of success. It also requires the efforts and coordination of people of diverse expertise and experience. Failure may occur at any stage and for multiple reasons, including unsuccessful preclinical and clinical development, inability to create a successful product formulation, and lack of a reproducible and controlled manufacturing process.

Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome.

Our only advanced product candidate, brilaroxazine, is still in development and will require extensive clinical testing before we are prepared to submit an NDA for regulatory approval. We cannot predict with any certainty if or when we might submit an NDA for regulatory approval for brilaroxazine or whether any such NDA will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We estimate that the Phase 3 clinical trials of brilaroxazine for schizophrenia indication will take at least eighteen months to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials, and the results of early clinical trials of brilaroxazine therefore may not be predictive of the results of our planned clinical studies.

The commencement and completion of clinical trials may be delayed by one or more factors, including:

- failure to obtain regulatory approval to commence a trial, including in other countries in the global portion of our planned clinical studies;
- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites;
- slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial;
- failure to manufacture sufficient quantities of a drug candidate for use in clinical trials;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, our management has limited prior experience in managing and completing late-stage clinical trials, and may not be able to successfully design and implement these trials or respond to adverse factors that may arise in the course of conducting these trials.

Further, we, the FDA or an institutional review board, or IRB, at a clinical trial site may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice, or GCP, regulations, that we are exposing participants to unacceptable health risks, or if the FDA finds deficiencies in our investigational new drug, or IND, submissions or the conduct of these trials.

Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of brilaroxazine could be harmed, and our ability to generate revenues from brilaroxazine may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations.

Moreover, while we are not currently intending to engage any principal investigators as advisors or consultants, it is conceivable that principal investigators for our clinical trials may serve as scientific advisors or consultants from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

The results of our clinical trials may not support our brilaroxazine, RP1208 and any future product candidate claims.

Even if our clinical trials are completed as planned, we cannot be certain that our results will support the safety and effectiveness of brilaroxazine for the treatment of schizophrenia or any other potential indication, including but not limited to PAH, IPF, BD, MDD, AD, PD, ADHD/ADD, or any of other product candidates, including RP1208. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. A failure of a clinical trial to meet its predetermined endpoints would likely cause us to abandon a product candidate and may delay development of any other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of our NDAs with the FDA and, ultimately, our ability to commercialize brilaroxazine, RP1208 or any future product candidate, and generate product revenues.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside of our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the study. Furthermore, any negative results we may report in clinical trials of our product candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same product candidate. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop brilaroxazine, RP1208 or any future product candidate, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

Any continued or worsening spread or future outbreaks of COVID-19 globally could adversely impact our clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Disruptions or restrictions on the ability of patients enrolled in our clinical studies to travel, or the ability of staff at study sites to travel, as well as temporary closures of our facilities or the facilities of our clinical trials partners and their contract manufacturers, would negatively impact our clinical trial activities.

The biopharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to change, including due to judicial challenges.

The U. S. biopharmaceutical industry is highly regulated and subject to frequent and substantial changes, including as a result of new judicial or government actions. Legislative and regulatory agendas as they relate to the biopharmaceutical industry are currently uncertain. Changes in the regulatory approval process, or substantial reductions in the personnel who oversee that process, could affect our ability to obtain regulatory approval for our product candidates or the timeline in which we can obtain that approval. We and our current and future third-party collaborators may rely on government programs or agencies, such as the National Institutes for Health ("NIH"), as a source of grant funding for scientific research relevant to our product candidates. Funding from government agencies such as the NIH can fluctuate and is subject to the political process, which is often unpredictable. Reductions in NIH grants to us or our third-party collaborators may adversely impact our ability to develop our existing product candidates and our ability to identify new product candidates. In addition, on June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision could have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework may increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies could be subject to increased litigation and judicial scrutiny. We cannot predict how other future federal or state legislative or administrative changes relating to healthcare reform or the biopharmaceutical industry, or the regulatory agencies that oversee the biopharmaceutical industry, will affect our business.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

Drug development is highly competitive and subject to rapid and significant technological advancements. As a significant unmet medical need exists for the treatment of schizophrenia, there are several large and small pharmaceutical companies focused on delivering therapeutics for the treatment of schizophrenia. Further, it is likely that additional drugs will become available in the future for the treatment of schizophrenia.

We are aware of other companies that are working to develop drugs that would compete against brilaroxazine for schizophrenia treatment. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing.

Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any product candidate that we may develop.

We will face competition from other drugs currently approved or that will be approved in the future for the treatment of schizophrenia. Therefore, our ability to compete successfully will depend largely on our ability to:

- develop and commercialize medicines that are superior to other products in the market;
- demonstrate through our clinical trials that brilaroxazine is differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain patent or other proprietary protection for our medicines;
- obtain required regulatory approvals;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for any product candidate it develops. The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make brilaroxazine less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize brilaroxazine, RP1208 or any other product candidates, and our ability to generate revenue will be materially impaired.

Brilaroxazine and the activities associated with its development and commercialization, including its design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for brilaroxazine will prevent us from commercializing it.

We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that none of brilaroxazine, RP1208 nor any other product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales.

Prior to submitting a new drug application ("NDA") to the FDA, a marketing authorization application, or MAA, to the EMA, or an equivalent application to other foreign regulatory authorities for approval of brilaroxazine, we will need to complete our clinical studies including the RECOVER-2 Trial.

We expect to rely on third-party CROs and consultants to assist us in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish brilaroxazine's safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

We have been granted orphan drug designation in the United States for brilaroxazine for the treatment of IPF and PAH. Upon receipt of regulatory approval, orphan drug status will provide us with seven years of market exclusivity in the United States under the Orphan Drug Act. However, there is no guarantee that the FDA will grant orphan drug designation for any of our drug candidates for any future indication, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation. Moreover, there can be no assurance that another company also holding orphan drug designation for the same indication or which may receive orphan drug designation in the future will not receive approval prior to when we do, in which case our competitor would have the benefit of the seven years of market exclusivity, and we would be unable to commercialize our product candidate for the same indication until the expiration of such seven-year period. Even if we are the first to obtain approval for the orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during our seven-year period of exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the Unites States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for brilaroxazine for any additional indications or for RP1208, if we elect to seek such designation.

Brilaroxazine, RP1208 and any future product candidate may cause adverse effects or have other properties that could delay or prevent its regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events caused by brilaroxazine, RP1208 and any future product candidate could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in our clinical trials for brilaroxazine, RP1208 or any future product candidates, our ability to obtain regulatory approval for such product candidates may be negatively impacted.

Furthermore, if any of our product candidates are approved and then cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or require a REMS to impose restrictions on its distribution or other risk management measures;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or to conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients;
- we could elect to discontinue the sale of our products; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing brilaroxazine, RP1208 and any future product candidate.

The results of pre-clinical testing are not necessarily predictive of future results, and RP1208 and other product candidates may not have favorable results in our planned clinical trials.

Any positive results from our pre-clinical testing of RP1208 and any future product candidates may not necessarily be predictive of the results from our planned clinical trials. Many companies in the pharmaceutical industry have suffered significant setbacks in clinical trials after achieving positive results in pre-clinical development, and we cannot be certain that we will not face similar setbacks. The pre-clinical data we have obtained for RP1208 may not predict results from studies in larger numbers of subjects drawn from more diverse populations or in a commercial setting, and also may not predict the ability of RP1208 to achieve its intended goals, or to do so safely.

Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials nonetheless failed to obtain FDA or EMA approval. If we fail to produce positive results in our clinical trials, the development timeline and regulatory approval and commercialization prospects for our products and, correspondingly, our business and financial prospects, would be materially adversely affected.

Changes in product candidate manufacturing or formulation may result in additional costs, delay or non-approval.

In order to win approval, we must show that we are able to manufacture our products in a controlled, consistent and quality manner. Should we not be able to do so, our products will not be approved. In addition, as product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. During the course of a development program, sponsors may also change the contract manufacturers used to produce the product candidates. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of clinical trials. Such changes may also require additional testing, notification or approval by the FDA, EMA or other regulatory authorities. This could delay completion of clinical trials; require the conduct of bridging clinical trials or studies, or the repetition of one or more clinical trials; increase clinical trial costs; delay or prevent approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

We have orphan drug designation for some of our product candidates in the United States and may seek such designation for other candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same indication for that drug during that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We cannot assure you that any future application for orphan drug designation with respect to any product candidate will be granted. If we are unable to obtain orphan drug designation in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.

We may seek fast track designation or priority review of applications for approval of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even if we do receive fast track designation or priority review, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Any breakthrough therapy designation granted by the FDA for our product candidate may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidate will receive marketing approval.

We may apply for a breakthrough therapy designation for one or more of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval if the relevant criteria are met.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe our product candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Even if we obtain FDA approval for brilaroxazine, RP1208 or any future product candidate in the United States, we may never obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize our full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we obtain regulatory approval for brilaroxazine, RP1208 or any future product candidate, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and current GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including any requirement to implement a REMS. If brilaroxazine, RP1208 or any future product candidate receives marketing approval, the accompanying label may limit the approved use of our drug candidate, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of brilaroxazine, RP1208 or any future product candidate. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

Even if brilaroxazine, RP1208 or any future product candidate receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

If brilaroxazine, RP1208 or any future product candidate receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenues and become profitable. The degree of market acceptance of brilaroxazine, RP1208 or any future product candidate, if approved for commercial sale, will depend on a number of factors, including, but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of brilaroxazine, RP1208 or any future product candidate, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of this product to find market acceptance would harm our business and require us to seek additional financing.

If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third-parties, we may not be successful in commercializing brilaroxazine, RP1208 or any future product candidate, if approved.

We do not have any infrastructure for the sales, marketing or distribution of our products, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product that may be approved, we must build our sales, distribution, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any product for which we have obtained marketing approval, we will need a sales and marketing organization.

We expect to build a focused sales, distribution and marketing infrastructure to market brilaroxazine, RP1208 or any future product candidate in the United States, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of brilaroxazine, RP1208 or any future product candidate. For example, if the commercial launch of brilaroxazine, RP1208 or any future product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe any drugs; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of brilaroxazine in markets outside of the United States. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in the product and such collaborator's ability to successfully market and sell the product. We intend to pursue collaborative arrangements regarding the sale and marketing of brilaroxazine, RP1208 or any future product candidate, if approved, for markets outside of the United States; however, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of brilaroxazine, RP1208 or any future product candidate we may be forced to delay the potential commercialization of brilaroxazine, RP1208 or any future product candidate or reduce the scope of our sales or marketing activities for brilaroxazine, RP1208 or any future product candidate. If we elect to increase our expenditures to fund commercialization activities itself, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring brilaroxazine, RP1208 or any future product candidate to market or generate product revenue. We could enter into arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to brilaroxazine, RP1208 or any future product candidate or otherwise agree to terms unfavorable to it, any of which may have an adverse effect on our business, operating results and prospects.

If we are unable to establish adequate sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing brilaroxazine, RP1208 or any future product candidate and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If brilaroxazine, RP1208 or any future product candidate is approved for commercialization, we intend to enter into agreements with third parties to market it in certain jurisdictions outside the United States. We expect that it will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply.

Our subsidiary may not be in compliance with the laws of foreign countries, and it may face penalties and fines imposed by the Indian government.

We have not retained local counsel to assess whether our subsidiary, Reviva Pharmaceuticals India Private Limited, is in compliance with applicable local law. There can be no assurance that we will be able to initially meet such requirements or maintain compliance with the laws and regulations of each foreign country in which our subsidiary operates. As a result, we, Reviva Pharmaceuticals India Private Limited and our other subsidiary may be subject to adverse legal consequences, including but not limited to penalties and fines, which could adversely affect our business, financial condition or results of operations.

We are subject to U.S. foreign investment regulations, which may impose additional burdens on or may limit certain investors' ability to purchase shares of our common stock in amounts deemed by the U.S. government to confer control, potentially making our common stock less attractive to investors, and may also impact our ability to generate revenues outside of the U.S.

In 2018, Congress passed the Foreign Investment Risk Review Modernization Act of 2018 ("FIRRMA"), which expanded the jurisdiction of the Committee on Foreign Investment in the United States ("CFIUS") to review direct or indirect foreign investments in U.S. companies. Among other things, FIRRMA empowers CFIUS to require certain foreign investors to make mandatory filings, permits CFIUS, to charge filing fees related to such filings, and empowers CFIUS to self-initiate national security reviews of foreign direct and indirect investments in U.S. companies. In the case that CFIUS determines an investment to be a threat to national security, CFIUS has the power to unwind or place restrictions on the investment. Any such restrictions on the ability to purchase shares of our common stock may have the effect of delaying or deterring any particular investment and could also affect the price that some investors are willing to pay for our common stock. In addition, such restrictions could also limit the opportunity for our stockholders to receive a premium for their shares of our common stock in relation to any potential change in control.

Our current and future relationships with foreign actors such as, health care and administrative professionals at foreign state owned hospitals or foreign government healthcare regulators will be subject to applicable anti-corruption laws regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers, may expose us to broadly applicable anti-corruption and anti-bribery laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we market, sell and distribute our products. Such laws include the Foreign Corrupt Practices Act of 1977, as amended (the "FCPA") prohibits any offer, payment, promise to pay or authorization to pay any money, gift or thing of value to any Foreign Official, political party, or candidate for office for the purpose of influencing any act or failure to act by the recipient, in his or her official capacity, in order to obtain or retain business, or inducing the recipient to use influence to affect a decision of a foreign government or agency in order to obtain or retain business for anyone. The FCPA also imposes recordkeeping requirements and internal controls provisions, which, among other things, require the issuer to keep accurate books, records, and accounts.

Our current and future relationships with investigators, health care professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to it, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize brilaroxazine, RP1208 or any future product candidate and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system and efforts to control health care costs, including drug prices, that could have a significant negative impact on our business, including preventing, limiting or delaying regulatory approval of our drug candidates and reducing the sales and profits derived from our products once they are approved.

For example, in the United States, the Patient Protection and Affordable Care Act of 2010 ("ACA") substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Many provisions of ACA impact the biopharmaceutical industry, including that in order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS.

We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be.

Coverage and adequate reimbursement may not be available for brilaroxazine, RP1208 or any future product candidate, which could make it difficult for us to sell our products profitably.

Market acceptance and sales of any product candidates that we develop, will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities and private health insurers. Third-party payors decide which drugs they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a plan-by-plan basis. One payer's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, and on what tier of its formulary the drug will be placed. The position of a drug on a formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidates that we develop.

Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell any future drugs profitably. These legislative and regulatory changes may negatively impact the reimbursement for any future drugs, following approval.

Risks Related to Our Dependence on Third Parties

We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of brilaroxazine, RP1208 and any future product candidate.

We do not have experience in drug formulation or manufacturing and do not own or operate, and do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. We also will rely on third-party manufacturers to supply us with sufficient quantities of brilaroxazine to be used, if approved, for the commercialization of brilaroxazine. If we are unable to initiate or continue our relationship with one or more of these third-party contractors, we could experience delays in our development efforts as we locate and qualify new manufacturers.

Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our product candidates, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with cGMP and similar foreign standards;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell brilaroxazine, RP1208 or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

Any of these events could lead to clinical trial delays, failure to obtain regulatory approval or impact our ability to successfully commercialize our products. Some of these events could be the basis for FDA action, including injunction, recall, seizure, or total or partial suspension of production.

We rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance.

We rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs will be required to comply with the Good Laboratory Practices and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs will be independent contractors and not our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

If our relationship with any one or more of these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

Changes in the U.S. political and regulatory environment could affect availability of government funding that we or our third-party collaborators may rely on, which could negatively impact the development of our product candidates.

We and our current and future third-party collaborators may rely on government programs or agencies, such as the NIH, as a source of grant funding for scientific research relevant to our product candidates. Funding from government agencies such as the NIH can fluctuate and is subject to the political process, which is often unpredictable. For example, on February 7, 2025, the NIH issued Notice Number NOT-OD-25-068, a guidance document pronouncing that funding in NIH grants to cover certain indirect costs would be capped at 15% for existing and future grant recipients, a rate that is substantially lower than the existing rates. Reductions in NIH grants to us and our third-party collaborators may adversely impact our ability to develop our existing product candidates and our ability to identify new product candidates.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our drug development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to brilaroxazine, RP1208 and any future product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover brilaroxazine, RP1208 or any future product candidate in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover brilaroxazine, RP1208 or any future product candidate, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents that we own could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If the patent applications we hold with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for brilaroxazine, RP1208 or any future product candidate, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize future drugs. Any such outcome could have a material adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make or the first to file the inventions claimed in our owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, inter parties review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse may in some cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering brilaroxazine, RP1208 or any future product candidate. Our competitors might be able to enter the market, which would have an adverse effect on our business.

Third-party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights, may delay or prevent the development and commercialization of brilaroxazine, RP1208 and any future product candidate.

Our commercial success depends in part on avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter party review, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. Based on our general knowledge in this field of technology and based on the patent prosecution of brilaroxazine conducted in the United States and in foreign countries, we do not believe that there are valid patents which contain granted claims that could be asserted with respect to brilaroxazine, however, we may be incorrect.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

Because patent applications can take many years to issue, there may be currently pending patent applications filed by third parties which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our future drugs or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly. The initiation of a claim against a third-party may also cause the third-party to bring counter claims against us, such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace.

Grounds for a patent invalidity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar invalidity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of securities that may be issued by us.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting and defending patents covering brilaroxazine, RP1208 and any future product candidate throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we expect to rely on third parties to manufacture brilaroxazine, RP1208 and any future product candidates, and we expect to collaborate with third parties on the manufacturing of brilaroxazine, RP1208 and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks Related to Our Securities

Our officers, directors, and principal stockholders exercise significant control over our Company, and will control our Company for the foreseeable future, including the outcome of matters requiring stockholder approval.

Our officers, directors and principal stockholders who beneficially own more than 5% of our common stock, in the aggregate, beneficially own shares representing approximately 34.16% of our outstanding capital stock as of March 14, 2025. As a result, such entities and individuals have the ability, acting together, to control the election of our directors and the outcome of corporate actions requiring stockholder approval, such as: (i) a merger or a sale of our Company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our certificate of incorporation and bylaws. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders with interests different from those entities and individuals. These individuals also have significant control over our business, policies and affairs as officers and directors of our Company.

An active trading market for our common stock or warrants may not be sustained.

An active trading market for our common stock or warrants may not develop or continue or, if developed, may not be sustained. The lack of an active market for our common stock or warrants may impair investors' ability to sell their common stock or warrants at the time they wish to sell them or at a price that they consider reasonable, may reduce the fair market value of their shares of common stock or warrants and may impair our ability to raise capital to continue to fund operations by selling securities and may impair our ability to acquire additional intellectual property assets by using our securities as consideration.

A sale of a substantial number of shares of our common stock or warrants in the public market could cause the market price of our common stock or warrants to drop significantly, even if our business is doing well.

The price of our common stock or warrants could decline as a result of sales of a large number of shares of our common stock or warrants or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

In addition, in the future, we may issue additional shares of common stock, warrants or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock or warrants to decline.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock or warrants, the price of our common stock or warrants could decline.

The trading market for our common stock and warrants relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity analysts downgrade our common stock or warrants or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

The price of our common stock or warrants may be volatile, which could subject us to securities class action litigation and our stockholders could incur substantial losses.

The market price for our common stock or warrants may be volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our securities;
- additions or departures of key management or other personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our products;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our securities by us, our insiders or our other stockholders; and
- general economic, market or political conditions in the United States or elsewhere.

In particular, the market prices of pharmaceutical companies like ours have been highly volatile due to factors, including, but not limited to:

- any delay or failure to conduct a clinical trial for a company's product or to receive approval from the FDA and other regulatory agencies;
- developments or disputes concerning a company's intellectual property rights;
- technological innovations of such companies or their competitors;
- changes in market valuations of similar companies
- announcements by such companies or their competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents;
- failure to complete significant transactions or collaborate with vendors in manufacturing a product; and
- proposals for legislation that would place restrictions on the price of pharmaceutical products.

These and other market and industry factors may cause the market price and demand for our common stock and warrants to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock or warrants and may otherwise negatively affect the liquidity of our common stock or warrants. In addition, the stock market in general and Nasdaq have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

If we fail to maintain compliance with the requirements of The Nasdaq Capital Market for continued listing, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is listed for trading on The Nasdaq Capital Market. There can be no assurance that we will be able to continue to maintain compliance with the Nasdaq continued listing requirements, and if we are unable to maintain compliance with the continued listing requirements, including the $1.00 Minimum Bid Price Requirement set forth in Nasdaq Listing Rule 5550(a)(2), our securities may be delisted from Nasdaq, which could reduce the liquidity of our common stock materially and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and business development opportunities. Such a delisting likely would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from Nasdaq, our common stock may no longer be recognized as a "covered security" and we would be subject to regulation in each state in which we offer our securities. Thus, delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our common stock.

Certain of our warrants are accounted for as liabilities and the changes in value of such warrants could have a material effect on our financial results.

On April 12, 2021, the SEC Staff released the Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies (the "Statement"). In the Statement, SEC Staff made the observation that certain contractual provisions included in many Special Purpose Acquisition Company warrant agreements may result in such warrants needing to be classified as a liability rather than as equity. As a result of the SEC Statement, we reevaluated the accounting treatment of our Private Warrants and Public Warrants, and determined to classify the Private Warrants as derivative liabilities measured at fair value, with changes in fair value each period reported in earnings.

As a result, included on our consolidated balance sheet as of December 31, 2024 contained elsewhere in this Annual Report on Form 10-K, are derivative liabilities related to embedded features contained within our Private Warrants. Accounting Standards Codification 815, Derivatives and Hedging ("ASC 815"), provides for the remeasurement of the fair value of such derivatives at each balance sheet date, with a resulting non-cash gain or loss related to the change in the fair value being recognized in other income (expense) in the statements of operations. As a result of the recurring fair value measurement, our consolidated financial statements and results of operations may fluctuate quarterly, based on factors, which are outside of our control. Due to the recurring fair value remeasurement, we expect that we will recognize non-cash gains or losses on our Private Warrants each reporting period and that the amount of such gains or losses could be material.

We will incur significantly increased costs and devote substantial management time as a result of operating as a public company particularly since we are no longer an "emerging growth company."

As a relatively new public company, we now incur significant legal, accounting and other expenses that we did not incur when we were a private company. For example, we are required to comply with certain of the requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as amended, as well as rules and regulations subsequently implemented by the SEC, including the ongoing maintenance of effective disclosure and financial controls and compliant corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. In addition, since we no longer qualify as an emerging growth company (our eligibility to qualify as an emerging growth company ended on December 31, 2023, the last day of the fiscal year following the fifth anniversary of Tenzing's initial public offering), management have had (and we expect them to continue) to devote more time and the Company has (and we expect it to continue) to incur additional cost to comply with the more stringent reporting requirements applicable to companies that are not emerging growth companies. Also, if we become subject to the requirements applicable to accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, our compliance burdens and expenses will further increase. We have not yet completed the process of compiling the system and processing documentation needed to comply with such requirements applicable to accelerated and large accelerated filers. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. In that regard, we currently do not have an internal audit function, and although we have contracted for certain accounting staff, we may need to hire or contract for additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, particularly as the Company grows.

We cannot predict or estimate the amount of additional costs we may incur as a result of being a public company, including as a result of our exit from emerging growth company status, or the timing of such costs.

We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, any gains from an investment in our common stock will likely depend on appreciation in the price of our common stock.

We have never declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, investors must rely on sales of their common stock and warrants after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock or warrants will appreciate in value or even maintain the price at which the stockholders have purchased their shares or warrants.

Upon our dissolution, the stockholders may not recoup all or any portion of their investment.

In the event of our liquidation, dissolution or winding-up, whether voluntary or involuntary, the proceeds and/or assets of remaining after giving effect to such transaction, and the payment of all debts and liabilities and distributions required to be made to holders of any outstanding preferred stock will then be distributed to the stockholders of common stock on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of our common stock, or any amounts, upon such a liquidation, dissolution or winding-up.

Our certificate of incorporation, as amended and restated, allows for our board of directors to create new series of preferred stock without further approval by the stockholders, which could adversely affect the rights of the holders of our common stock.

Our board of directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our board of directors has the authority to issue up to 10 million shares of preferred stock without further stockholder approval. As a result, our board of directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation and the right to receive dividend payments before dividends are distributed to the holders of our common stock. In addition, our board of directors could authorize the issuance of a series of preferred stock that has greater voting power than the common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to existing stockholders.

Delaware law and our certificate of incorporation, as amended and restated, and our bylaws contain certain provisions, including anti-takeover provisions that limit the ability of stockholders to take certain actions and could delay or discourage takeover attempts that stockholders may consider favorable.

Our certificate of incorporation, as amended and restated, and our bylaws, and the Delaware General Corporation Law, as amended (the "DGCL"), contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition deemed undesirable by our board of directors and therefore depress the trading price of our common stock. These provisions could also make it difficult for stockholders to take certain actions, including electing directors who are not nominated by the current members of our board of directors or taking other corporate actions, including effecting changes in management. Among other things, our certificate of incorporation, as amended and restated, and our bylaws include provisions regarding:

- the ability of our board of directors to issue shares of preferred stock, including "blank check" preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the limitation of the liability of, and the indemnification of, our directors and officers;
- the right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent (except as required for holders of future series of preferred stock), which forces stockholder action to be taken at an annual or special meeting of stockholders and could delay the ability of stockholders to force consideration of a stockholder proposal or to take action, including the removal of directors;
- the requirement that a special meeting of stockholders may be called only by our board of directors, which could delay the ability of stockholders to force consideration of a proposal or to take action, including the removal of directors;
- controlling the procedures for the conduct and scheduling of our board of directors and stockholder meetings;
- the requirement for the affirmative vote of holders of at least a majority of the voting power of all of the voting power of the then outstanding shares of the voting stock, voting as a single class, to amend, alter, change or repeal any provision of our bylaws and certain provisions in our certificate of incorporation, as amended and restated, respectively, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in our board of directors and also may inhibit the ability of an acquirer to effect such amendments to facilitate an unsolicited takeover attempt;
- the ability of our board of directors to amend our bylaws by an affirmative vote of a majority of our board of directors, which may allow our board of directors to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend our bylaws to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in our board of directors and also may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our board of directors or management. In addition, as a Delaware corporation, we will generally be subject to provisions of Delaware law, including Section 203 of the DGCL.

Any provision of our certificate of incorporation, as amended and restated, our bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our certificate of incorporation, as amended and restated, designates a state or federal court located within the State of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, or employees.

Our certificate of incorporation, as amended and restated, provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware, or if such court does not have subject matter jurisdiction, any other court located in the State of Delaware with subject matter jurisdiction, will be the sole and exclusive forum for (i) any derivative action or proceeding brought on the Company's behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, other employee or stockholder of the Company to the Company or the Company's stockholders, (iii) any action asserting a claim against the Company or our officers or directors arising pursuant to any provision of the DGCL or our certificate of incorporation, as amended and restated, or our bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim against the Company or any director or officer of the Company governed by the internal affairs doctrine of the law of the State of Delaware; provided, that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state court sitting in the State of Delaware. Additionally, our certificate of incorporation, as amended and restated, provides that, unless the Company consents to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act; provided, however, that such provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management

We, like other companies in our industry, face several cybersecurity risks in connection with our business. Our business strategy, results of operations, and financial condition have not, to date, been affected by risks from cybersecurity threats. During the reporting period, we have not experienced any material cyber incidents, nor have we experienced a series of immaterial incidents, which would require disclosure.

In the ordinary course of our business, it is our strategy to minimize our data footprint; however, appropriate protocols are initiated and assessed to ensure proper security of the data we own. Cybersecurity partners, including assessors, consultants, advisors and other third-party service providers, are a key part of our cybersecurity risk management strategy and infrastructure. We partner with industry recognized cybersecurity providers leveraging third-party technology and expertise and engage with these partners to monitor and maintain the performance and effectiveness of IT assets, data and services. We do not use, store and process data of our partners, collaborators, and vendors in our facilities and instead outsource such functions to expert third parties. Our intellectual property data is not stored on site. We only maintain a bare minimum amount of employee data. By fully outsourcing our IT environment and placing it within expert third party software-as-a-service, human resource, and clinical providers, our primary means of avoiding cyber risk is not having sensitive data within our enterprise. We have implemented a cybersecurity risk management program that is designed to identify, assess, and mitigate risks from cybersecurity threats to data and our systems. Our cybersecurity risk management program incorporates several components, which include multifactor authentication, access control, data segregation, password requirements, email filtering, activity logging, malware protection, and an endpoint security tool. Additionally, we maintain a cyber insurance policy.

The Company's management team has prior experience selecting, deploying, and overseeing cybersecurity technologies, initiatives, and processes directly or via selection of strategic third-party partners. All third parties are reviewed by our chief executive officer ("CEO"), and including to ensure that they have risk management procedures in place, including physical, procedural, and technical safeguards. Additionally, the SOC 1 and/or SOC 2 reports of all critical vendors are obtained and analyzed on an annual basis in order to determine the effectiveness of third-party control environments.

Governance

Under the ultimate direction of our CEO, with oversight from our board of directors, we maintain a security governance structure to evaluate and address cyber risk. Our CEO regularly consults with our Chief Financial Officer ("CFO") and third-party IT consultant who have expertise in cybersecurity to develop strategies to assess, address and align cybersecurity efforts with our business objectives and operational requirements. Our board of directors, in conjunction with third-party IT and cybersecurity service providers are responsible for oversight and administration of our cyber risk management program, and for informing senior management and other relevant participants in these processes regarding the prevention, detection, mitigation and remediation of cybersecurity incidents. Our leadership team has experience selecting and overseeing cybersecurity technologies, initiatives, and processes directly or via selection of strategic third-party partners.

Our board of directors is responsible for the oversight of cybersecurity risk management, including oversight of information security and cybersecurity threats and related compliance and disclosure requirements. On an annual and as-needed basis, our CEO provides an update to our board of directors regarding our cybersecurity risk management program, including any critical cybersecurity risks, ongoing cybersecurity initiatives and strategies, and applicable regulatory requirements and industry standards. Our CEO also notifies our audit committee of any cybersecurity incidents (suspected or actual) and provides updates on the incidents as well as cybersecurity risk mitigation activities as appropriate.

ITEM 2. PROPERTIES

Our principal offices are located at 10080 N. Wolfe Road, Suite SW3-200, Cupertino, California 95014. The facility is subject to a lease which was extended through December 31, 2025. The facility is used for office space only, and we believe the facility is adequate for our foreseeable needs. We operate primarily as a virtual company.

ITEM 3. LEGAL PROCEEDINGS.

We may, from time to time, become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. Except as described above, we are currently not aware of any such legal proceedings or claims that may be, individually or in the aggregate, material to us.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

Part II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock and our listed warrants trade on Nasdaq under the symbols "RVPH" and "RVPHW," respectively.

Dividends

We have never declared or paid cash dividends on our common stock. We do not intend to declare or pay cash dividends on our common stock for the foreseeable future, but currently intend to retain any future earnings to fund the development and growth of our business. The payment of cash dividends, if any, on the common stock will rest solely within the discretion of our board of directors and will depend, among other things, upon our earnings, capital requirements, financial condition, and other relevant factors

Record Holders

As of December 31, 2024, there were approximately 187 holders of record of our common stock and 2 holders of record of our listed warrants. These numbers do not include beneficial owners whose shares or warrants were held in street name. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

Unregistered Sales of Equity Securities

None except as previously reported.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The information in this Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") should be read in conjunction with the Company's consolidated financial statements and the related notes set forth in Item 1 of Part I of this Annual Report on Form 10-K, our MD&A set forth in Item 7 of Part II of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and the Company's consolidated financial statements and related notes set forth in Item 8 of Part II of such Annual Report on Form 10-K. See Part II, Item 1A, "Risk Factors," below and "Cautionary Note Regarding Forward-Looking Statements," and the information referenced therein, for a description of risks that we face and important factors that we believe could cause actual results to differ materially from those in our forward-looking statements. All amounts and percentages are approximate due to rounding and all dollars in the text are in millions, except per share amounts or where otherwise noted. When we cross-reference to a "Note," we are referring to our "Notes to Consolidated Financial Statements" included in Part I, Item 1, of this Annual Report on Form 10-K, unless the context indicates otherwise.

All statements other than statements of historical fact included in this section regarding our financial position, business strategy and the plans and objectives of management for future operations, are forward-looking statements. When used in this section, words such as "anticipate," "believe," "estimate," "expect," "intend" and similar expressions, as they relate to our management, identify forward-looking statements. Such forward-looking statements are based on the beliefs of management, as well as assumptions made by, and information currently available to, our management. Actual results could differ materially from those contemplated by the forward- looking statements as a result of certain factors detailed herein. All subsequent written or oral forward-looking statements attributable to us or persons acting on our behalf are qualified in their entirety by this paragraph.

Company Overview

We are a late-stage pharmaceutical company that discovers, develops, and seeks to commercialize next-generation therapeutics for diseases representing significant unmet medical needs and burdens to society, patients, and their families. Our current pipeline focuses on the central nervous system, inflammatory, and cardiometabolic diseases. We use a chemical genomics driven technology platform and proprietary chemistry to develop new medicines. Our pipeline currently has two drug candidates, brilaroxazine (RP5063) and RP1208. Both are new chemical entities discovered in-house. We have been granted composition of matter patents for both brilaroxazine and RP1208 in the United States (U.S.), Europe, and several other countries.

Our lead drug candidate, brilaroxazine, is in clinical development and is intended to treat multiple neuropsychiatric indications. These include schizophrenia, bipolar disorder ("BD"), major depressive disorder ("MDD"), attention-deficit/hyperactivity disorder ("ADHD"), behavioral and psychotic symptoms of dementia and Alzheimer's disease ("BPSD"), and Parkinson's disease psychosis ("PDP"). Furthermore, brilaroxazine is also ready for clinical development for two respiratory indications - pulmonary arterial hypertension ("PAH") and idiopathic pulmonary fibrosis ("IPF"). The U.S. Food and Drug Administration ("FDA") granted Orphan Drug Designation to brilaroxazine for the treatment of PAH in November 2016 and IPF in April 2018. Brilaroxazine also is in preclinical development for the treatment of psoriasis.

Our primary focus is to complete the clinical development of brilaroxazine for the treatment of acute and maintenance schizophrenia.

On October 30, 2023, we announced positive topline results from our Phase 3 RECOVER 1 trial (the "RECOVER-1 Trial"), which is a global Phase 3, randomized, double-blind, placebo-controlled, multicenter study designed to assess the safety and efficacy of brilaroxazine in approximately 400 patients with acute schizophrenia compared to placebo. See "Phase 3 RECOVER-1 Data" below for more details on brilaroxazine development.

Subject to the receipt of additional financing, we may also continue the clinical development of brilaroxazine for the treatment of BD, MDD, ADHD, BPSD, PDP, PAH and IPF. Moreover, subject to the receipt of additional financing, we may also advance the development of our second drug candidate, RP1208, for the treatment of depression and obesity.

Phase 3 RECOVER-1 Data

On October 30, 2023, we announced positive topline results and successful completion of our pivotal RECOVER-1 Trial evaluating the efficacy, safety and tolerability of once-daily brilaroxazine, a serotonin dopamine signaling modulator in adults with schizophrenia. The trial successfully met its primary endpoint at the 50 mg dose, with brilaroxazine at that dose achieving a statistically significant and clinically meaningful 10.1-point reduction in Positive and Negative Syndrome Scale (PANSS) total score compared to placebo (-23.9 brilaroxazine 50 mg vs. -13.8 placebo, $p<0.001$) at week 4. Brilaroxazine also achieved statistically significant and clinically meaningful reductions in all major symptom domains and secondary endpoints at week 4 with the 50 mg dose vs. placebo. The 15 mg dose of brilaroxazine was numerically superior to placebo on the primary endpoint and most secondary endpoints, and reached statistical significance on two key secondary endpoints.

Key statistically significant and clinically meaningful improvements with brilaroxazine vs. placebo in patients with schizophrenia and a mean PANSS total score of 97-99 at baseline include:

Primary and Secondary Endpoints	Point Reduction/ Improvement for Brilaroxazine 50 mg vs. Placebo at Week 4	Cohen's d Effect Size	P Value
PANSS Total Score	10.1	*0.6*	*<0.001*
Positive Symptoms	2.8	*0.5*	*<0.001*
Negative Symptoms ("NS")	2.0	*0.4*	*0.003*
NS Marder Factor	2.1	*0.4*	*0.002*
PANSS Social Cognition	1.6	*0.5*	*<0.001*
PANSS Excitement/Agitation	2.1	*0.5*	*<0.001*
Personal and Social Performance	6.3	*0.5*	*<0.001*
CGI-S score	≥1	*0.5*	*<0.001*

Key clinical safety and tolerability findings of brilaroxazine support a well-tolerated safety profile

- No drug related serious adverse events (SAEs) or treatment-emergent SAEs (TESAEs) observed or major safety concerns reported for brilaroxazine after 4 weeks of treatment;
- No incidence of suicidal ideation;
- No significant change in bodyweight and blood glucose levels;
- Significant decrease in cholesterol, LDL and increase in HDL compared to placebo;
- Significant decrease in prolactin and no change in thyroid levels compared to placebo;
- Akathisia and extrapyramidal symptoms <1% reported for brilaroxazine 50 mg and none for 15 mg;
- Common brilaroxazine treatment-emergent adverse events (TEAEs) were headache (<6%) and somnolence (<7.5%) generally transient in nature; and
- Low discontinuation rates with brilaroxazine that were less than placebo (16% in brilaroxazine 50mg and 19% in brilaroxazine 15mg vs. 22% placebo).

The clinical development plan for brilaroxazine also includes the completed positive Phase 2 REFRESH trial, an ongoing 1-year open label extension (“OLE”) trial evaluating long-term safety and tolerability, and a soon to be initiated registrational global, randomized 4-week Phase 3 RECOVER-2 trial (the “RECOVER-2 Trial”). We reported positive preliminary topline data from our OLE in December 2024, with the OLE expected to complete in Q2-2025, and we expect to initiate the registrational RECOVER-2 Trial in mid-2025, subject to receipt of additional financing, with completion anticipated in the third quarter of 2026. RECOVER-2 was originally designed as a 6-week study, but after discussion between Reviva and the FDA, the agency has agreed that it can be conducted as a 4-week study. In addition, the FDA indicated that it will require a long-term randomized withdrawal study post-approval to support maintenance of effect. Data from these brilaroxazine clinical trials will potentially support the planned NDA submission to the FDA in the fourth quarter of 2026.

Open Label Extension (OLE) Trial Enrollment Update

The OLE portion of the RECOVER Study is being conducted globally at multiple centers to assess the safety, and efficacy of brilaroxazine at flexible doses of 15, 30 or 50 mg, administered once daily for 52-weeks (1-year) in patients with stable schizophrenia. The OLE included both rollover participants from the double-blind portion of RECOVER study and de novo participants with stable schizophrenia. Long-term safety data from a minimum of 100 patients who have completed 1-year of treatment is a requirement for brilaroxazine's NDA submission to the FDA.

In November 2024, we provided the following enrollment update on our ongoing OLE evaluating the long-term safety and tolerability of brilaroxazine in patients with schizophrenia.

- Global trial progressing well;
- 108 patients have completed 1-year (12-month) of treatment;
- Over 250 patients have completed 6-months of treatment;
- Blood and digital biomarkers designed to independently support efficacy;
- Long-term safety data from 100 patients who have completed 12 months of treatment is a requirement for brilaroxazine's NDA submission to the FDA; and

On December 16, 2024, we announced positive preliminary topline data from our OLE evaluating the long-term safety and tolerability of brilaroxazine in patients with schizophrenia. Administration of brilaroxazine once daily led to robust broad-spectrum efficacy that was sustained over 1 year. Brilaroxazine was generally well tolerated with no single side effect >5% and favorable compliance, with a discontinuation rate of 35% in the OLE part of this study. All three doses of brilaroxazine (15 mg, 30 mg and 50 mg) tested were efficacious and generally well-tolerated.

Key safety, efficacy and compliance findings for pooled analysis of brilaroxazine at 15, 30, and 50 mg include:

- A total number of 435 patients were enrolled in the OLE across three dose groups: 139 in brilaroxazine 15 mg, 155 in brilaroxazine 30mg and 141 in brilaroxazine 50mg
- 156 (35.86%) rollover participants from the double-blind portion of the Phase 3 trial, while 279 (64.13%) de novo participants enrolled in the OLE
- Preliminary efficacy results are presented for 113 patients who completed 52 weeks (1 year) of treatment; preliminary safety results are presented for all 435 patients who enrolled in the OLE, including patients that are still participating in the trial

Brilaroxazine across doses improved major symptom domains of schizophrenia after 1-year of treatment:

- Dose dependent efficacy at the 15, 30, and 50 mg doses was observed, with decreases in PANSS total scores of -15.2, -18.6 and -20.8 points, respectively, from baseline to end-of-treatment at 52 -week (1 -year)
- Pooled data of brilaroxazine at the 15, 30, and 50 mg doses (N = 113) demonstrated clinically meaningful and sustained long-term (1-year) efficacy for schizophrenia with a significant decrease in PANSS total scores, PANSS positive symptoms, and PANSS negative symptoms compared to baseline
  - PANSS Total scores: 18.6-point decrease (71.6 → 53), $p \leq 0.0001$
  - PANSS Positive Symptoms: 5.2-point decrease (17.7 → 12.5), $p \leq 0.0001$
  - PANSS Negative Symptoms: 4.5-point decrease (19.5 → 15.0), $p \leq 0.0001$
- Brilaroxazine demonstrated strong sustained efficacy from acute through maintenance treatment over 1 -year with a decrease in PANSS Total score in rollover patients from the double-blind portion of the trial
  - ≥30-point decrease of PANSS total in 86.76% of patients
  - ≥40-point decrease of PANSS total in 64.70% of patients
  - ≥50-point decrease of PANSS total in 33.82% of patients

Long-term clinical safety, tolerability and adherence findings of brilaroxazine administered for up to one year support a well-tolerated safety profile:

- 15.2% of participants reported at least one treatment-related adverse event (TRAE), which were mostly mild (12.2%) or moderate (3%) in severity and transient in nature
- Most common TRAEs ≥1% were weight increase (3.2%), insomnia (1.8%) and somnolence (1.6%)
- Brilaroxazine was not associated with any clinically meaningful changes in movement disorder scales over 1 -year treatment
- No drug-related serious adverse events (SAEs) observed or major safety concerns reported for brilaroxazine after up to 1 -year of treatment; 3 serious adverse events were reported and none were related to brilaroxazine treatment
- Treatment discontinuation rate of 35% reported in this OLE, primarily due to withdrawal of consent (22%), participant lost to follow up (7%), and treatment-related adverse events (1.6%)

Collectively, the findings from the OLE (52-week/1-year) portion of the Phase 3 RECOVER study further strengthen the safety, efficacy and treatment adherence findings from the double-blind (4-week) portion of RECOVER.

Recent Developments

May 2024 Registered Direct Offering

On May 28, 2024, we entered into a securities purchase agreement (the "Purchase Agreement"), pursuant to which we issued and sold an aggregate of 1,898,734 shares of our common stock and warrants to purchase up to 1,898,734 shares of our common stock (the "May 2024 Warrants") at a combined offering price of $1.58 per share of common stock and accompanying May 2024 Warrants in a registered direct offering ("May 2024 Offering"). The May 2024 Warrants have an exercise price of $1.455 per share, are immediately exercisable and expire five years following the date of issuance. The net proceeds to the Company from the May 2024 Offering were $2.8 million, after deducting placement offering costs, agent fees and expenses and other offering expenses payable by the Company, of $0.4 million. On May 29, 2024, we closed the May 2024 Offering.

In connection with the May 2024 Offering, we also agreed to amend certain existing warrants held by the investor in the May 2024 Offering to purchase up to an aggregate of 1,365,854 shares of our common stock that were previously issued to the investor in November 2023, with an exercise price of $5.00 per share, for $0.125 per amended warrant, so that the amended warrants have a reduced exercise price of $1.455 per share and expire five years following the closing of the May 2024 Offering.

August 2024 Underwritten Offering

On August 20, 2024, we entered into an underwriting agreement (the "Underwriting Agreement") with Titan Partners Group LLC, a division of American Capital Partners, LLC, as the underwriter, relating to the offering, issuance and sale of (i) 3,276,262 shares of common stock, (ii) pre-funded warrants (the "August 2024 Pre-Funded Warrants") exercisable for an aggregate of up to 1,485,643 shares of common stock, and (iii) warrants (the "August 2024 Warrants") exercisable for an aggregate of 4,761,905 shares of common stock (the "August 2024 Offering"). The public offering price for each share of common stock and accompanying August 2024 Warrant to purchase one share of common stock (including the pricing for the warrant repricing described below) was $1.05, and the public offering price for each August 2024 Pre-Funded Warrant and accompanying August 2024 Warrant to purchase one share of common stock was $1.0499. The net proceeds to the Company from the August 2024 Offering were approximately $3.6 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, of approximately $1.4 million. The August 2024 Offering closed on August 22, 2024.

Upon the closing of the August 2024 Offering, we issued to the Underwriter warrants to purchase up to 238,095 shares of common stock (the "August 2024 Underwriter Warrants"). The August 2024 Underwriter Warrants will be exercisable at an exercise price of $1.3125 per share and are exercisable during the five-year period commencing six months after the closing date of the August 2024 Offering.

In connection with the August 2024 Offering, on August 20, 2024, the Company entered into a warrant amendment agreement (the "August 2024 Warrant Amendment Agreement") with the purchaser of the August 2024 Pre-Funded Warrants pursuant to which the Company agreed to amend the purchaser's (i) warrants to purchase up to 2,536,586 shares of common stock at an exercise price of $5.00 per share issued in November of 2023 and (ii) warrants to purchase up to 2,199,975 shares of common stock at an exercise price of $4.125 per share issued in June of 2021 (together, the "August 2024 Existing Warrants"), in consideration for such investor's participation in the August 2024 Offering and the payment of $0.125 per August 2024 Existing Warrant (which amount is included in the $1.05 offering price above) to (i) lower the exercise price of the August 2024 Existing Warrants to $0.7964 per share and (ii) amend the expiration date of the August 2024 Existing Warrants to five years following the closing of the August 2024 Offering.

December 2024 Underwritten Offering

On December 16, 2024, the Company entered into an underwriting agreement (the "December Underwriting Agreement") with Citizens JMP Securities, LLC, as the underwriter (the "Underwriter"), relating to the offering, issuance and sale (the "December 2024 Underwritten Offering") of (i) an aggregate of 12,000,000 shares of the Company's common stock, par value $0.0001 per share ("Common Stock"), (ii) Series A warrants exercisable for an aggregate of up to 6,000,000 shares of Common Stock (the "Series A Common Stock Warrants") and (iii) Series B warrants exercisable for an aggregate of up to 12,000,000 shares of Common Stock (the "Series B Common Stock Warrants" and together with the Series A Common Warrants, the "December 2024 Common Stock Warrants").

Each share of Common Stock was sold together with (i) a Series A Common Stock Warrant to purchase 0.5 of a share of Common Stock and (ii) a Series B Common Stock Warrant to purchase one share of Common Stock, at a combined public offering price of $1.50 per share of Common Stock and accompanying December 2024 Common Stock Warrants. The Series A Common Stock Warrants are exercisable immediately, expire six months from the date of issuance on June 18, 2025, and have an exercise price of $1.50 per whole share. The Series B Common Stock Warrants are exercisable immediately, expire 5 years from the date of issuance on December 18, 2029, and have an exercise price of $1.50 per share. The net proceeds to the Company from the Offering were approximately $16.5 million, after deducting placement offering costs, agent fees and expenses and other offering expenses payable by the Company of approximately $1.5 million.

Financial Overview

We are a clinical-stage biopharmaceutical company and have not generated any revenues from the sale of products. We have never been profitable and have incurred losses since inception. As of December 31, 2024, we had a working capital surplus of approximately $0.1 million, an accumulated deficit of $164.3 million and cash and cash equivalents on hand of approximately $13.5 million. Our net loss for the years ended December 31, 2024 and 2023, was approximately $29.9 million and $39.3 million, respectively. We expect to incur significant expenses and increased operating losses for the next several years. We expect our expenses to increase in connection with our ongoing activities to research, develop and commercialize our product candidates. Furthermore, we continue to expect to incur additional costs associated with operating as a public company, which may increase now that we have exited emerging growth company status as of December 31, 2023, and as we continue our efforts to remediate the material weaknesses in our internal control over financial reporting that we identified as more particularly described in this Annual Report on Form 10-K below in "Item 9A. Controls and Procedures". We will need to generate significant revenues to achieve profitability, and we may never do so.

We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- invest significantly to further research and develop, through clinical trials for brilaroxazine, including completion of the OLE, and our planned registrational RECOVER-2 Trial, and pre-clinical research for RP1208, and seek regulatory approval for our product candidates brilaroxazine and RP1208;
- identify and develop additional product candidates;
- hire additional clinical, scientific and management personnel;
- seek regulatory and marketing approvals for any product candidates that we may develop;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any drugs for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other drugs and technologies; and
- add operational, financial and management information systems and personnel, including personnel to support our product candidate development, and any future commercialization efforts, and our ongoing compliance with and maintenance of public company controls, procedures and regulatory requirements and standards. and including in connection with our continuing efforts to remediate the material weaknesses in our internal control over financial reporting that we identified as more particularly described in this Annual Report on Form 10-K below in "Item 9A. Controls and Procedures".

Research and Development Expenses

We focus our resources on research and development activities, including the conduct of preclinical and clinical studies and product development and expense such costs as they are incurred. We have not historically tracked or recorded research and development expenses on a project-by-project basis, primarily because we use our employee and infrastructure resources across multiple research and development projects, and it is not practical for us to allocate such costs on a project-by-project basis. Our research and development expenses primarily consist of clinical trial expenses and employee-related expenses, including deferred salaries, salaries, benefits and taxes for personnel in research and development functions.

The largest recurring component of our total operating expenses has historically been research and development activities. We expect our research and development expenses will increase for the next several years as we advance our development programs, pursue regulatory approval of our product candidates in the U.S. and other jurisdictions and prepare for potential commercialization, which would require a significant investment in costs related to contract manufacturing and inventory buildup.

Our primary product candidates and their current status is as follows:

Drug Candidate	Indication	Status
Brilaroxazine (RP5063)	Schizophrenia	Conducted pivotal Phase 3 RECOVER-1 and long-term safety studies. Topline data for the RECOVER-1 Trial announced October 30, 2023 -OLE positive preliminary topline data readout reported in December 2024, with OLE expected to complete in Q2-2025 -Phase 3 RECOVER-2 Trial expected initiation in mid-2025, subject to receipt of additional financing, with topline readout anticipated in the third quarter of 2026
Brilaroxazine	Bipolar Disorder	Phase 1 complete**
Brilaroxazine	Depression-MDD	Phase 1 complete**
Brilaroxazine	Alzheimer's (AD-Psychosis/Behavior)	Phase 1 complete**
Brilaroxazine	Parkinson's	Phase 1 complete**
Brilaroxazine	ADHD/ADD	Phase 1 complete**
Brilaroxazine	PAH	Phase 1 complete**
Brilaroxazine	IPF	Phase 1 complete**
Brilaroxazine	Psoriasis	In pre-clinical development
RP1208	Depression	Completed pre-clinical development studies, including in vitro receptor binding studies, animal efficacy studies, and PK studies. Compound ready for IND enabling studies.
RP1208	Obesity	Completed pre-clinical development studies, including in vitro receptor binding studies and PK studies. Compound ready for animal efficacy studies.

** We completed the Phase 1 clinical study for brilaroxazine prior to starting the Phase 2 study in schizophrenia and schizoaffective disorder, and completed our RECOVER-1 Trial for which we announced topline data in October 2023. In these three studies, we collected safety data for brilaroxazine in over 800 patients, including healthy subjects and patients with stable schizophrenia, acute schizophrenia and schizoaffective disorder. Generally, no separate Phase 1 study is required for conducting a Phase 2 study for an additional indication, provided the treatment doses in the Phase 2 study for an additional indication are within the range of doses tested in the previously completed Phase 1 study.

The successful development of our platform and product candidates is highly uncertain, and we may never succeed in achieving marketing approval for our product candidates brilaroxazine (RP5063), RP1208, or any future product candidates. In connection with the activities required to complete the development of brilaroxazine for schizophrenia, including our ongoing OLE and our planned registrational RECOVER-2 Trial, we expect to incur substantial additional costs over the 2025-2026 period to take us through the submission of the planned NDA for brilaroxazine, together with additional costs post-NDA submission in preparation of potential commercialization if approved. We expect our clinical costs in connection with the development of brilaroxazine for schizophrenia may total approximately $67 million over the next approximately three years, consisting of our estimated costs for (i) completion of our OLE, (ii) our RECOVER-2 Trial through the planned NDA submission, and (iii) additional Research & Development costs (primarily associated with consulting, scientific, research and other expenses in support of the OLE and RECOVER-2 Trials through the planned NDA as well as certain activities in preparation of potential commercialization if the product attains approval). The foregoing forecasted amount of expenses is an estimate based on numerous factors and information available to management as of today, and is subject to change. The actual amount of such expenses could be materially higher or lower than the forecasted amount. The foregoing statements regarding estimates of forecasted future costs and expenses represent forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements." At this time, other than providing reasonable estimates and forecasts based on information available to us of what we expect future costs may be in connection with the RECOVER-2 Trial and OLE and certain associated expenses and other future activities needed to continue to develop brilaroxazine, we cannot reasonably estimate the nature, timing, or costs of the efforts necessary to finish developing any of our product candidates or the period in which material net cash, if any, from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing therapeutics, including the uncertainty of:

- the scope, rate of progress, expense, and results of clinical trials;
- the scope, rate of progress, and expense of process development and manufacturing;
- preclinical and other research activities; and
- the timing of regulatory approvals.

General Administrative Expenses

General and administrative expenses primarily consist of payroll and related costs for employees in executive, business development, finance, and administrative functions. Other significant general and administrative expenses include professional fees for accounting and legal services.

We expect general and administrative expenses to increase as we expand infrastructure and continue the development of our clinical programs. Other increases could potentially include increased costs for director and officer liability insurance, costs related to the hiring of additional personnel, and increased fees for directors, outside consultants, lawyers, and accountants. We expect to incur significant costs to comply with corporate governance, internal controls, and similar requirements applicable to public companies.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of our consolidated financial statements requires management 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 consolidated financial statements, and the reported amounts of expenses during the period. Significant items subject to such estimates and assumptions include clinical trial costs, fair value of stock-based compensation, and fair value of warrants. Our actual results could differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 2, Summary of Significant Accounting Policies and Basis of Presentation, to the consolidated financial statements included in Item 8 of this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical to assist stockholders and investors reading the consolidated financial statements in fully understanding and evaluating our financial condition and results of operation..

Clinical Trial Costs

We record clinical trial costs as they are incurred. For any unbilled costs as of each reporting date, we determine the amounts to accrue by obtaining reports from the Company's CRO's and communicating with our personnel and suppliers to identify services that have been performed, but not yet billed. We further validate the completeness of our accruals by reconciling payments and invoices, and reviewing vendor contracts and purchase orders. As necessary, we obtain milestones and percentage completion reports from vendors and will estimate the level of service performed and the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of the actual cost.

Our estimated accrued expenses are based on facts and circumstances known to us at that time. We will confirm the accuracy of our estimates with the service providers and adjust if necessary. The significant estimates in our accrued clinical trial costs include the calculation of patient visits incurred, but not yet reported by the vendor. The calculation involves the use of key inputs and assumptions such as estimated budget, estimated unreported costs based on historical trending of reported costs to date, and projected costs remaining until the conclusion of the trials.

Stock-based Compensation

We record stock-based compensation based on the requirements of ASC 718, *Share-Based Payments* ("ASC 718"), which requires recognition in the consolidated financial statements of the cost of employee and director services received in exchange for an award of equity instruments over the period the employee or director is required to perform the services in exchange for the award (presumptively, the vesting period). ASC 718 also requires measurement of the cost of employee and director services received in exchange for an award based on the grant-date fair value of the award. The fair value of the award is recognized as expense based upon the vesting terms of the award over the requisite service period. We account for forfeited awards as they occur.

In determining the fair value of awards, we utilize the Black-Scholes-Merton model using assumptions regarding volatility of the Company's common share price, expected term, expected divided rate, and risk-free interest rates as described below:

- Expected term: The expected term represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method.

- Expected volatility: Expected volatility is based on historical stock volatility data for a peer set of similar public companies with sufficient trading history, over the expected term of the awards.

- Expected dividend: The Black-Scholes-Merton valuation model calls for a single expected dividend yield as an input. We have never paid dividends and have no plans to pay dividends.

- Risk-free interest rate: The risk-free interest rate used in the Black-Scholes-Merton valuation method is based on the U.S. Treasury zero-coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

Fair Value Measurements of Warrants

In determining the fair value of all equity classified warrants, the Company utilizes the Black-Scholes-Merton model using assumptions regarding volatility of the Company's common share price, expected term of the warrants, expected divided rate, and risk-free interest rates. In determining the fair value of liability classified warrants, the Company utilizes a Lattice model using assumptions regarding volatility of the Company's common share price, expected term of the warrants, expected dividend, and risk-free interest rates. The assumptions are described as:

- Expected term: The Company's expected term represents the period between the valuation date and the expiration date of the warrant, however if an estimated liquidation event is expected to occur and the warrants are effected by said liquidation event, the period between the valuation date and that event would be used instead.

- Expected volatility: Expected volatility for equity classified awards is based on historical stock volatility data for a peer set of similar public companies with sufficient trading history, over the expected term of the warrant. Expected volatility for liability classified warrants is based on the volatility implied by the public warrant market price when sufficient data is available, otherwise it is based on a peer set of similar public companies.

- Expected dividend: The Black-Scholes-Merton valuation model calls for a single expected dividend yield as an input. The Company has never paid dividends and has no plans to pay dividends.

- Risk-free interest rate: The risk-free interest rate used in the Black-Scholes-Merton valuation method is based on the U.S. Treasury zero-coupon issues in effect at the valuation date for periods corresponding with the expected term of the warrant.

Results of Operations

Comparison of the years ended December 31, 2024 and 2023:

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023:

	Year Ended December 31,		Change	Change
	2024	2023	Amount	Percentage
Operating expenses				
Research and development	$ 22,907,368	$ 31,419,817	$(8,512,449)	(27.1)%
General and administrative	7,891,521	8,083,819	(192,298)	2.4%
Total operating expenses	30,798,889	39,503,636		
Loss from operations	(30,798,889)	(39,503,636)		
Gain (loss) on remeasurement of warrant liabilities	717,645	(239,216)	956,861	(400.0)%
Interest expense	(18,497)	(33,725)	(15,228)	(45.2)%
Interest income	361,369	398,413	(37,044)	(9.3)%
Other (expense) income, net	(160,916)	134,276	(295,192)	(219.8)%
Total other income, net	899,601	259,748		
Loss before provision for income taxes	(29,899,288)	(39,243,888)		
Provision for income taxes	19,514	16,949	2,565	15.1%
Net loss	$(29,918,802)	$(39,260,837)		

Research and Development Expenses

Research and development costs are expensed as incurred. These expenses represent both internal and external costs.

For the years ended December 31, 2024 and 2023, research and development expenses were approximately $22.9 million and $31.4 million, respectively. Specifically, during the years ended December 31, 2024 and 2023, our research and development costs consisted primarily of the following costs associated with our key research and development projects for advancing the clinical development of brilaroxazine during the reporting periods, namely our OLE and RECOVER-1 Trials for our Phase 3 clinical study for brilaroxazine: (i) internal salaries, wages and other payroll related costs for employees involved in research and development activities, of approximately $2.3 million and $3.3 million, respectively; (ii) internal share-based compensation expenses with respect to employees involved in research and development activities, of approximately $1.0 million and $1.5 million, respectively; (iii) other research and development related costs, of an insignificant amount and $0.1 million, respectively; and (iv) external research and development expenses, of approximately $19.6 million and $26.6 million, respectively (which includes clinical (including clinical consulting) research and development costs of approximately $15.5 million and $22.3 million, respectively, non-clinical safety related costs of approximately $1.3 million and $1.9 million, respectively, non-clinical manufacturing related costs of approximately $2.4 million and $1.7 million, respectively, and non-clinical consulting and other related costs of approximately $0.4 million and $0.6 million, respectively).

The decrease in research and development expenses for the year ended December 31, 2024 as compared to the year ended December 31, 2023 was primarily attributed to a decrease in external research and development costs, including clinical consulting, due to completion of the RECOVER-1 Trial on October 31, 2023, offset by additional external research and development costs related to a change order entered into on September 25, 2024 which increased the scope of certain services provided by a clinical research organization.

We expect our research and development activities to increase as we develop our existing product candidates and potentially acquire new product candidates, reflecting increasing costs associated with our ongoing operations, including expenses associated with activities required to complete the development of brilaroxazine in schizophrenia including completion of our OLE Trial and our planned registrational RECOVER-2 Trial, to take us through the submission of the planned NDA for brilaroxazine, together with additional costs post-NDA submission in preparation of potential commercialization if approved. For additional information, please see the discussion appearing above in the introductory section of this Part I-Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operation.

General and Administrative Expenses

For the years ended December 31, 2024 and 2023, general and administrative expenses were approximately $7.9 million and $8.1 million, respectively. Specifically, during the years ended December 31, 2024 and 2023, our general and administrative expenses consisted primarily of: (i) stock-based compensation expense of approximately $0.7 million and $2.0 million, respectively; (ii) consultant and professional expenses of approximately $3.4 million and $1.8 million, respectively; (iii) legal expenses of approximately $1.2 million and $1.0 million, respectively; (iv) employee related expenses of approximately $1.8 million and $2.0 million, respectively; (v) D&O insurance expenses of $0.5 million approximately and $0.9 million, respectively, and (vi) other general and administrative expenses of approximately $0.3 million and $0.4 million, respectively.

Gain (Loss) on Remeasurement of Warrant Liabilities

We recognized a remeasurement of warrant liabilities gain of approximately $0.7 million and a loss of $0.2 million for the years ended December 31, 2024 and 2023, respectively. The approximate $0.7 million gain on remeasurement of warrant liabilities for the year ended December 31, 2024 resulted from the decrease in the calculated fair value of the warrants, principally as a result of the decrease in our stock price during the year ended December 31, 2024. The approximate $0.2 million loss on remeasurement of warrant liabilities for the year ended December 31, 2023 resulted from the increase in the calculated fair value of the warrants, principally as a result of the increase in stock price during the year ended December 31, 2023.

Interest Expense

We incurred interest expense of approximately $18 thousand and $34 thousand for the years ended December 31, 2024 and 2023, respectively. The decrease in interest expense is attributed to a decrease in the interest rate and balance for short term debt obtained by the Company in January 2024 related to Director & Officer liability insurance policy premiums.

Interest Income

Interest income was approximately $361 thousand and $398 thousand for the years ended December 31, 2024 and 2023, respectively. Interest income slightly decreased by $37 thousand primarily due to the lower cash and cash equivalents balance for the year ended December 31, 2024 compared to the year ended December 31, 2023.

Other (Expense) Income, net

Other expense, net incurred was approximately $161 thousand for the year ended December 31, 2024 and other income, net incurred was approximately $134 thousand for the year ended December 31, 2023. The change from income to an expense was approximately $295 thousand and was primarily attributable to a foreign currency translation loss from negative foreign currency fluctuations related to the consolidation of the Company's Indian subsidiary.

Liquidity and Capital Resources

	Year Ended December 31,		Change	
	2024	2023	Amount	Percentage
Balance Sheet Data:				
Cash and cash equivalents	$ 13,476,331	$ 23,367,456	$ (9,891,125)	(42.3)%
Working capital	81,861	6,525,371	(6,443,510)	(98.7)%
Total assets	15,503,088	23,700,388	(8,197,300)	(34.6)%
Total stockholders' equity	812,572	5,718,716	(4,906,144)	(85.8)%
Statement of Cash Flow Data:				
Net cash used in operating activities	$(33,543,916)	$(28,324,353)	$ (5,219,563)	18.4%
Net cash provided by financing activities	23,652,791	33,171,953	(9,519,162)	(28.7)%
Net (decrease) increase in cash and cash equivalents	$ (9,891,125)	$ 4,847,600	$(14,738,725)	(304.0)%

Capital Resources

We have funded our operations to date primarily from the issuance and sale of our equity and convertible equity securities. As of December 31, 2024, we had cash and cash equivalents of approximately $13.5 million. To fund our current operating plans, we will need to raise significant additional capital. Our existing cash and cash equivalents will not be sufficient for us to complete development of our product candidates and, if applicable, to prepare for commercializing any product candidate that may receive approval. Accordingly, we will continue to require substantial additional capital beyond our existing cash to continue our clinical development and potential commercialization activities. We believe that we have adequate cash on hand to cover anticipated outlays into the second quarter of 2025, but will need additional fundraising activities and cash on hand during the second quarter of 2025. We have based this estimate, however, on assumptions that may prove to be wrong, and could spend available financial resources much faster than we currently expect. We will need to raise additional funds to continue funding our development efforts and operations. We intend to secure such additional funding, although there are no guarantees or commitments for additional funding. These conditions raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date the consolidated financial statements are issued. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. We will seek to fund our operations through public or private equity, debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition, and our ability to pursue our business strategy, and our ability to continue as a going concern. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we continue our research and preclinical and clinical development of our product candidates; expand the scope of our current studies for our product candidates; initiate additional preclinical, clinical or other studies for our product candidates; change or add additional manufacturers or suppliers; seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical studies; seek to identify, evaluate and validate additional product candidates; acquire or in-license other product candidates and technologies; maintain, protect and expand our intellectual property portfolio; attract and retain skilled personnel; add operational, financial and management information systems and personnel, including personnel to support our product candidate development, and any future commercialization efforts, and our ongoing compliance with and maintenance of public company controls, procedures and regulatory requirements and standards, including in connection with our ongoing remediation efforts regarding the material weaknesses in our internal controls as disclosed in this Annual Report including in Part II, Item 9B hereof; and experience any delays or encounter issues with any of the above. See also the discussion set forth under the caption "Financial Overview" appearing in this Management's Discussion and Analysis of Financial Condition and Results of Operation section above.

In January 2024, we obtained financing for certain Director & Officer liability insurance policy premiums. The governing agreement assigns the lender a first priority lien on and security interest in the financed policies and any additional premium required in the financed policies. The total premiums, taxes, and fees financed was $519 thousand with an annual percentage interest rate of 7.99% and has a term of 10 months, with ten payments inclusive of interest, payable on a monthly basis through November 2024.

In December 2024, the Company obtained new financing for the renewal of these policies. The total premiums, taxes, and fees financed was $458 thousand. The financing arrangement has an annual percentage interest rate of 7.90% and a term of 10 months, with ten payments, inclusive of interest, payable on a monthly basis beginning January 2025 through October 2025.

During the year ended December 31, 2024, there were 1,485,643 pre-funded warrants exercised at an exercise price of $0.0001 per warrant share.

On May 29, 2024, we completed a registered direct offering (the "May 2024 Offering") of 1,898,734 shares of our common stock and warrants to purchase up to 1,898,734 shares of our common stock (the "May 2024 Common Stock Warrants") at a combined offering price of $1.58 per share of common stock and accompanying May 2024 Common Stock Warrants. The May 2024 Warrants have an exercise price of $1.455 per share, are immediately exercisable, and have a term of 5 years and expire on May 29, 2029. The net proceeds to us from the May 2024 Offering were $2.8 million, after deducting placement offering costs, agent fees and expenses and other offering expenses payable by the Company, of approximately $0.4 million.

On August 22, 2024, we completed an underwritten offering for the issuance and sale of (i) 3,276,262 shares of our common stock, (ii) pre-funded warrants (the "August 2024 Pre-Funded Warrants") exercisable for an aggregate of up to 1,485,643 shares of common Stock, and (iii) warrants (the "August 2024 Warrants") exercisable for an aggregate of 4,761,905 shares of common stock (the "August 2024 Offering"). The public offering price for each share of common stock and accompanying August 2024 Warrants to purchase one share of common stock (including the pricing for warrant repricing) was $1.05 per share, and the public offering for each August 2024 Pre-Funded Warrants and accompanying August 2024 Warrants to purchase one share of common stock was $1.0499 per share. The net proceeds to the Company from the August 2024 Offering were approximately $3.6 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. Total issuance costs were approximately $1.4 million, which included the $0.2 million fair value of the underwriter warrants issued.

On December 18, 2024, we completed an underwritten offering, for the issuance and sale of an aggregate of (i) 12,000,000 shares of our common stock, (ii) Series A warrants (the "Series A Common Stock Warrants") exercisable for an aggregate of up to 6,000,000 shares of common stock, and (iii) Series B warrants (the "Series B Common Stock Warrants" together with the Series A Common Warrants, the "December 2024 Common Stock Warrants") exercisable for an aggregate of up to 12,000,000 shares of common stock, for net proceeds of $16.5 million (the "December 2024 Underwritten Offering"), after deducting placement offering costs, agent fees and expenses and other offering expenses payable by the Company of $1.5 million. Each share of common stock was sold together with (i) a Series A Common Stock Warrant to purchase 0.5 of a share of common stock and (ii) a Series B Common Stock Warrant to purchase one share of common stock, at a combined public offering price of $1.50 per share of common stock and accompanying December 2024 Common Stock Warrants. The Series A Common Stock Warrants are exercisable immediately, expire six months from the date of issuance on June 18, 2025, and have an exercise price of $1.50 per whole share. The Series B Common Stock Warrants are exercisable immediately, expire 5 years from the date of issuance on December 18, 2029, and have an exercise price of $1.50 per share.

Until such time as we can generate substantial product revenue, if ever, we expect to finance our cash needs through a combination of equity or debt financings and collaboration agreements. We do not currently have any committed external sources of capital. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we raise additional funds through collaboration agreements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs or make changes to our operating plan, or curtail or cease operations. We will need to generate significant revenues to achieve profitability, and we may never do so.

Cash Flows

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31, 2024 was approximately $33.5 million, consisting primarily of a net loss of approximately $29.9 million, adjusted for non-cash items, including a change in fair value of warrant liabilities gain of approximately $0.7 million, and stock-based compensation expense of approximately $1.6 million, coupled with a decrease in our operating assets and liabilities totaling approximately $4.5 million. The $4.5 million decrease in net operating assets and liabilities was primarily due to a decrease in accrued clinical expenses and other accrued expenses coupled with an increase in prepaid clinical trial costs, an increase in prepaid expenses and other current assets, and an increase in accounts payable.

Net cash used in operating activities for the year ended December 31, 2023, was approximately $28.3 million, consisting primarily of a net loss of approximately $39.3 million, adjusted for non-cash items, including a change in fair value of warrant liabilities loss of approximately $0.2 million, and stock-based compensation expense of approximately $3.4 million, coupled with an increase in our operating assets and liabilities totaling approximately $7.3 million. The $7.3 million increase in net operating assets and liabilities was primarily due to an increase in accounts payable coupled with an increase in accrued expenses and other current liabilities and decrease in prepaid expenses and other current assets.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2024 was approximately $23.7 million. Cash provided by financing activities was attributable to approximately $23.2 million in proceeds from the issuance of common stock, common stock warrants, prefunded warrants, and from modification of existing warrants, in offerings, net of issuance costs, and $1.0 million of proceeds from the issuance of short-term debt, which is offset by repayments on the short-term debt of approximately $0.5 million.

Net cash provided by financing activities for the year ended December 31, 2023 was approximately $33.2 million. Cash provided by financing activities was attributable to approximately $27.5 million in proceeds from the issuance of common stock, common stock warrants, prefunded warrants, in offerings, net of issuance costs, $0.7 million in proceeds from the issuance of short-term debt and approximately $5.7 million in proceeds from the exercise of warrants for common stock, slightly offset by the repayments of short-term debt of approximately $0.7 million.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information called for by this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item appears in a separate section of this Annual Report on Form 10-K beginning on page F-1 and is incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, and the rules and regulations thereunder, 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 our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and implementation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2024. Based on that evaluation, management concluded that as of December 31, 2024, the Company did not maintain effective disclosure controls and procedures because of the material weaknesses in internal control over financial reporting described below.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in I*nternal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Because of the material weaknesses described below, based on the results of management's evaluation, management has concluded that our internal control over financial reporting was ineffective as of December 31, 2024.

We identified the following entity-level material weaknesses. We have an ineffective control environment, including an insufficient number of personnel with an appropriate level of knowledge and experience to create the proper environment for effective internal control over financial reporting, and did not maintain the other components of the COSO framework, including appropriate risk assessment, control activities, information and communication, and monitoring activities components relating to (i) sufficiency of processes related to identifying and analyzing risks to the achievement of objectives, including technology, across the entity, (ii) developing general control activities over technology to support the achievement of objectives across the entity, (iii) sufficiency of selecting and developing control activities that contribute to the mitigation of risks to the achievement of objectives to acceptable levels and (iv) sufficiency of monitoring activities to ascertain whether the components of internal control are present and functioning.

The entity-level material weaknesses contributed to other material weaknesses within our system of internal control over financial reporting as follows:

- We did not design and maintain effective information technology (IT) general controls for certain information systems supporting our key financial reporting processes. Specifically, we did not design and maintain (a) change management controls to ensure that program and data changes affecting financial applications and underlying accounting records are identified, tested, authorized and implemented appropriately, (b) access controls to ensure appropriate IT segregation of duties are maintained that adequately restrict and segregate privileged access between environments which support development and production, (c) controls to monitor on an on-going basis for the proper segregation of privileged access between environments which support development and production and (d) operations controls to ensure appropriate interfacing between systems. As a result, IT application controls and business process controls (automated and manual) that are dependent on the ineffective IT general controls, or that rely on data produced from systems impacted by the ineffective IT general controls, are also deemed ineffective.
- We did not design and maintain effective process-level controls, which affects substantially all account balances and disclosures.

These material weaknesses have a pervasive impact and consequently, impact control activities over all financial statement account balances, classes of transactions, and disclosures.

Management's Remediation Measures

We are committed to continuing to improve our internal control over financial reporting, and also our IT general controls. As of the date hereof, we have commenced procedures to remediate the material weaknesses, including engaging a third-party consulting firm to assist with the enhancement of IT general controls over information systems relevant to financial reporting,

including privileged access and segregation of duties; and with continued realignment of existing personnel to strengthen management's review and documentation over internal control over financial reporting.

We will continue to monitor the design and effectiveness of these procedures and controls and make any further changes we determine appropriate.

Notwithstanding the existence of the material weaknesses as described above, we believe that the Consolidated Financial Statements (as restated) in this Annual Report fairly present, in all material respects, our financial position, results of operations, and cash flow as of the dates, and for the periods presented, in conformity with GAAP.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm on our internal control over financial reporting because we are currently a non-accelerated filer and are therefore not required to provide an attestation report on our internal control over financial reporting until such time as we are an accelerated filer or large accelerated filer.

Changes in Internal Control Over Financial Reporting

Except as discussed above, there was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fourth quarter of the year ended December 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. OTHER INFORMATION

During the fiscal quarter ended December 31, 2024, none of our officers or directors, as those terms are defined in Rule 16a-1(f), adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable

Part III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following sets forth certain information with respect to our executive officers and directors.

Name	Age	Position
Laxminarayan Bhat	59	President, Chief Executive Officer, and Director
Narayan Prabhu	53	Chief Financial Officer
Parag Saxena	69	Chairman of the Board of Directors
Richard Margolin	74	Director
Purav Patel	42	Director
Les Funtleyder	55	Director

Management

Laxminarayan Bhat - see description below under the heading "Directors."

Narayan Prabhu joined the Company as Chief Financial Officer in December 2020. Prior to this, from May 2019 to December 2020, Mr. Prabhu had served as an independent consultant providing Interim Chief Financial Officer and Controller services. Mr. Prabhu previously served as the Chief Financial Officer of Sony Biotechnology Inc., a biotechnology company focused on reagents, flow cytometry and spectral imaging from November 2014 to April 2019. From September 2009 to October 2014, Mr. Prabhu served as the M&A Controller at Cisco Systems, Inc. (NASDAQ: CSCO). Mr. Prabhu is a CPA and received his B.S. in Accounting & Finance from Indiana University at Bloomington - Kelley School of Business and MBA from the University of California at Berkeley - Haas School of Business.

Directors

Laxminarayan Bhat is the founder of our Company and has served as our President, Chief Executive Officer and as a member of our board of directors since December 2020. Prior to this, Dr. Bhat served as President, Chief Executive Officer and a director of Old Reviva since its inception in 2006. From 2000 to 2004, Dr. Bhat served as research scientist at XenoPort, Inc., now a part of Arbor Pharmaceuticals, LLC (NYSE: ABR), a public company engaged in the pharmaceuticals business. Dr. Bhat also served as a research scientist, from 2004 to 2006, at ARYx Therapeutics Inc, (previously trading under OTCM: ARYX), a former public company that focused on the development of pharmaceutical products. From 1997 to 2000, Dr. Bhat served as a post-doctoral researcher in the Drug Discovery Program at the Higuchi Biosciences Center, a biomedical research center at the University of Kansas. Dr. Bhat has over 20 years' experience in drug discovery and development. Dr. Bhat has received a global post-doctoral training at the University of Kansas, USA, the Georg-August-Universität, Göttingen, Germany and the Université du Maine, France. In 1995, he was selected for the Alexander von Humboldt fellowship, an internationally recognized award for young scientists to pursue advanced research in Germany. Dr. Bhat received his Ph.D. in synthetic organic chemistry from the Central University (NEHU), India.

We believe Dr. Bhat's history as the founder of Reviva and his experience in drug discovery and development qualifies him to serve on our board of directors.

Parag Saxena has served as Chairman of our board of directors since December 2020, and prior to this, served as Chairman of the board of directors of Tenzing since 2018. Mr. Saxena has extensive investment experience in the U.S. and in the Indian subcontinent. Mr. Saxena co-founded private equity investment management firms Vedanta Management LP (or Vedanta) and NSR Advisors in 2006. He is the Managing Partner and Chief Executive Officer of both firms. Previously, he was Chief Executive Officer of INVESCO Private Capital (and its predecessor firms), a venture capital firm in the U.S. During his 23-year tenure, over 300 investments were made, including Amgen, Costco, PictureTel, Polycom, Staples and Starbucks. Mr. Saxena led more than 90 investments for INVESCO Private Capital (and its predecessor firms), a third of which went on to become public companies. These investments include Alkermes, Celgene, Genomic Health, Indigo, Masimo, Transgenomic, Xenon Pharmaceuticals, Amber Networks, ARM Holdings, MetroPCS, and Volterra. Mr. Saxena has served on committees advising the Prime Minister of India on foreign direct investments, and the Planning Commission of India on venture capital. He is a Director of the Indian Institute of Technology, Bombay's Heritage Fund and was a Trustee of the Bharatiya Vidya Bhavan. He is on the Advisory Board of the Center for Advanced Studies on India at the University of Pennsylvania and is on the Indian Advisory Council and President's Advisory Council on Biology and Medicine at Brown University. Mr. Saxena was the President of TiE Tri-State (NY, CT, NJ) from 2003 to 2010. He was also on Mayor Bloomberg's Applied Sciences NYC Advisory Committee. Mr. Saxena received an M.B.A. from the Wharton School of the University of Pennsylvania. He earned a B.Tech. from the Indian Institute of Technology, Bombay and an M.S. in Chemical Engineering from the West Virginia College of Graduate Studies.

We believe Mr. Saxena's deep financial, entrepreneurial and business expertise and extensive experience as a member of the boards and board committees of other public companies qualifies him to serve on our board of directors.

Les Funtleyder has served as a member of our board of directors since December 2020. Mr. Funtleyder has served as a member of the board of directors of Applied Therapeutics Inc. (NASDAQ: APLT), a clinical-stage biopharmaceutical company, since June 2016 and served as its interim Chief Financial Officer from December 2018 to April 2019. Mr. Funtleyder has also served as a healthcare portfolio manager at E Squared Capital Management, LLC since January 2014, a senior external advisor with McKinsey and Co. since June 2017, and a consulting partner at Bluecloud Health, a private equity healthcare fund, since December 2013. Mr. Funtleyder previously served as the director of strategic investments and communications of OPKO Health Inc. (NASDAQ: OPK), a publicly traded healthcare company, from April 2014 to June 2016. Mr. Funtleyder currently serves on the board of directors of several private healthcare companies and foundations. Mr. Funtleyder is also an adjunct professor of Healthcare Investing at Columbia University's School of Public Health. Mr. Funtleyder received his B.A. from Tulane University and MPH from Columbia University Mailman School of Public Health.

We believe Mr. Funtleyder's extensive experience managing and investing in the healthcare industry and his experience serving as the CFO of another publicly-traded pharmaceutical company qualifies him to serve on our board of directors.

Richard Margolin has served as a member of our board of directors since December 2020. Dr. Margolin currently serves as the Chief Medical Officer of TauC3 Biologics Ltd., a privately held British biopharmaceutical company since August 2023, and also served as its Senior Vice President, Translational Sciences and Clinical Development from February 2020 until July 2023. From January 2020 until December 2023, Dr. Margolin served as the Chief Medical Officer of Eikonizo Therapeutics, Inc., a biotechnology company, and he is the Founder and Principal Consultant of CNS Research Solutions LLC, a consulting firm supporting the development of novel therapeutics for CNS disorders since May 2018.. From December 2016 to April 2018, Dr. Margolin served as Executive Director, Internal Medicine Research Unit at Pfizer, Inc. (NYSE: PFE), a publicly-traded pharmaceutical company. From November 2013 to December 2016, Dr. Margolin served as the Vice President, Clinical Development at CereSpir, Inc., a biotechnology company. Previously, he held positions in two major pharmaceutical companies, and earlier in his career he held leadership positions in psychiatry departments of two major U.S. medical schools. Dr. Margolin earned his AB from Harvard College and his MD from the University of California, Irvine and received research training at the National Institutes of Health.

We believe Dr. Margolin's 30 years of experience in pharmaceutical research and development qualifies him to serve on our board of directors.

Purav Patel has served as a member of our board of directors since December 2020. Prior to this, Mr. Patel served as a director of Old Reviva since May 2017. Mr. Patel has also been Founder and Managing Partner of Buena Vista Fund I, a company engaged in the business of startup investments since 2014. Mr. Patel has over 17 years of experience in business operations and scaling startups. Mr. Patel serves on the board of directors of Pratham, a charitable organization with the mission to vastly improve the quality of education for underprivileged children and youth across India. Mr. Patel holds a Bachelor's Degree in Biology and Business from the University of Texas. Mr. Patel is skilled at financial analysis, business operations and fundraising.

We believe Mr. Patel's 15 years of knowledge of Reviva's history, team, investors and product candidates qualifies him to serve on our board of directors.

Committees of the Board of Directors

Our board of directors has an audit committee, compensation committee and nominating and corporate governance committee. All of the committees comply with all applicable requirements of the Sarbanes-Oxley Act, Nasdaq and SEC rules and regulations as further described below. The responsibilities of each of the committees of our board of directors is described below. Members will serve on these committees until their resignation or until as otherwise determined by our board of directors.

Audit Committee

The members of our audit committee are Mr. Funtleyder, Mr. Patel and Dr. Margolin, and Mr. Funtleyder serves as the chairperson of the audit committee. Each of the members of our audit committee satisfies the requirements for independence and financial literacy under the applicable rules and regulations of the SEC and rules of Nasdaq. We have determined that Mr. Funtleyder qualifies as an "audit committee financial expert" as defined in the SEC rules and satisfies the financial sophistication requirements of Nasdaq. Our audit committee is responsible for, among other things:

- appointing (and recommending that our board of directors submit for stockholder ratification, if applicable) compensating, retaining and overseeing the work performed by the independent auditor retained for the purpose of preparing or issuing an audit report or performing other audit or audit-related services;
- reviewing the performance and independence of the independent auditor;
- pre-approving all audit, review, and non-attest services to be provided to us or our subsidiaries by the independent auditor;
- discussing the scope and results of the audit with the independent registered public accounting firm and reviewing, with management and the independent registered public accounting firm, our interim and year-end consolidated financial statements;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing legal and regulatory compliance matters, including review of notifications from our CEO of any cybersecurity incidents (suspected or actual) and review of cybersecurity risk mitigation activities as appropriate;
- reviewing our policies on and oversees risk assessment and risk management, including enterprise risk management; and
- reviewing the adequacy and effectiveness of internal control policies and procedures and our disclosure controls and procedures.

Our board of directors has adopted a written charter for the audit committee which is available on our website.

Compensation Committee

The members of our compensation committee are Mr. Patel, Dr. Margolin and Mr. Saxena, and Mr. Patel serves as the chairperson of the compensation committee. Each of the members of our compensation committee meets the requirements for independence under the under the applicable rules and regulations of the SEC and rules of Nasdaq. Our compensation committee is responsible for, among other things:

- developing and reviewing compensation policies and practices applicable to executive officers;
- determining bases for and fixing compensation levels executive officers;

- reviewing, approving and determining compensation and benefits, including equity awards, to directors for service on our board of directors or any committee thereof; supervising, administering and evaluating incentive, equity-based and our other compensatory plans in which executive officers and key employees participate; and

- reviewing, approving and making recommendations to our board of directors regarding incentive compensation and equity compensation plans.

Our board of directors has adopted a written charter for the compensation committee which is available on our website.

Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are Mr. Saxena, Mr. Funtleyder and Mr. Patel, and Mr. Saxena serves as the chairperson of the nominating and corporate governance committee. Each of the members of the nominating and corporate governance committee meets the requirements for independence under the applicable rules and regulations of the SEC and rules of Nasdaq. Our nominating and corporate governance committee is responsible for, among other things:

- making recommendations to our board of directors regarding, the size of our board of directors, the composition of our board of directors, the process for filling vacancies on our board of directors and the tenure of our board of directors;

- making recommendations to our board of directors regarding the criteria for our board of directors and committee membership;

- developing, reviewing and overseeing our corporate governance practices and procedures; and

- making recommendations to our board of directors regarding corporate governance guidelines and matters.

Our board of directors has adopted a written charter for the nominating and corporate governance committee which is available on our website.

Director Independence

Our board of directors undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that Mr. Saxena, Mr. Funtleyder, Dr. Margolin, and Mr. Patel do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Rules of the Nasdaq Market and the SEC.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our employees, officers and directors. A current copy of the code is posted on the Corporate Governance section of our website, which is located at http://revivapharma.com/. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of such provisions applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and our directors, on our website identified above or in filings with the SEC.

Insider Trading Policy

We have adopted a Statement of Company Policy on Insider Trading and Policy Regarding Special Trading Procedures (the "Insider Trading Policy") that governs the purchase, sale and/or other dispositions of our securities by our directors, officers and employees, as well as other covered persons. We believe that the Insider Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to us. A copy of the Insider Trading Policy is filed as Exhibit 19.1 to this Form 10-K.

Limitations on Liability and Indemnification of Officers and Directors

The DGCL authorizes corporations to limit or eliminate the personal liability of directors to corporations and their stockholders for monetary damages for breaches of directors' fiduciary duties, subject to certain exceptions. Our certificate of incorporation, as amended and restated, includes a provision that eliminates the personal liability of directors for monetary damages for any breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Company or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL or (iv) for any transaction from which the director derived an improper personal benefit. The effect of these provisions is to eliminate the rights of the Company and its stockholders, through stockholders' derivative suits on the Company's behalf, to recover monetary damages from a director for breach of fiduciary duty as a director, including breaches resulting from grossly negligent behavior. However, exculpation does not apply to any director if the director has acted in bad faith, knowingly or intentionally violated the law, authorized illegal dividends or redemptions or derived an improper benefit from his or her actions as a director.

Our certificate of incorporation, as amended and restated, and our bylaws provide that we must indemnify and advance expenses to directors and officers to the fullest extent authorized by the DGCL. We are also expressly authorized to carry directors' and officers' liability insurance providing indemnification for directors, officers and certain employees for some liabilities. We believe that these indemnification and advancement provisions and insurance are useful to attract and retain qualified directors and executive officers.

The limitation of liability, indemnification and advancement provisions in our certificate of incorporation, as amended and restated, and our bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit the Company and its stockholders. In addition, your investment may be adversely affected to the extent we pays the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. We believe that these provisions, liability insurance and the indemnity agreements are necessary to attract and retain talented and experienced directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

There is currently no pending material litigation or proceeding involving any of our respective directors, officers or employees for which indemnification is sought.

ITEM 11. EXECUTIVE COMPENSATION

As we are currently a "smaller reporting company", we have opted to comply with the scaled down disclosure rules applicable to a "smaller reporting company", as such term is defined in the rules promulgated under the Securities Act, which require compensation disclosure for (i) our principal executive officer, (ii) our two most highly compensated executive officers, other than the principal executive officer, whose total compensation for 2024 exceeded $100,000 and who were serving as executive officers as of December 31, 2024, and (iii) up to two additional individuals for whom disclosure would have been provided pursuant to the foregoing clause (ii) but for the fact that the individual was not serving as an executive officer as of December 31, 2024. We refer to these individuals as "named executive officers." Our named executive officers for the year ended December 31, 2024 were:

- Laxminarayan Bhat, our Chief Executive Officer and President; and
- Narayan Prabhu, our Chief Financial Officer.

2024 Summary Compensation Table

The following table presents information regarding the total compensation awarded to, earned by, or paid to our named executive officers during the fiscal years ended December 31, 2024 and 2023.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option awards ($) (1)	Non-Equity Incentive Plan Compensation ($) (2)	Total ($)
Laxminarayan Bhat, PhD[3]	2024	450,000	157,500	—	—	607,500
Chief Executive Officer and President	2023	450,000	—	2,157,247	157,500	2,764,747
Narayan Prabhu[3]	2024	325,000	79,950	—	—	404,950
Chief Financial Officer	2023	325,000	—	827,838	95,940	1,248,778

(1) Amounts reflect the grant date fair value of option awards granted in 2024 and 2023 in accordance with Accounting Standards Codification Topic 718. For information regarding assumptions and key inputs underlying the valuation of equity awards, see Note 5 to our Consolidated Financial Statements included in this report. These amounts do not correspond to the actual value that may be received by the named executive officers if the stock options are exercised.

(2) Amounts reflect, in accordance with Accounting Standards Codification Topic 718, the grant date fair value of options to purchase the Company's common stock granted to the respective named executive officer in payment of the incentive bonus earned by each such named executive officer for fiscal 2023. The amount of incentive bonus earned for 2023 was determined by the Committee on September 15, 2024 and was paid in the form of fully vested options granted on such date in lieu of cash. The value of option grants was calculated on the Grant Date using the simplified method and based on the Black-Scholes-Merton option pricing model, with the inputs being a stock price of $1.20, an exercise price of $1.20, an expected term of 5 years, a risk-free rate of 3.37%, a volatility of 118% and an expected dividend of 0%. These amounts do not correspond to the actual value that may be received by the named executive officers if the stock options are exercised.

(3) Laxminarayan Bhat has served as Chief Executive Officer and President since the formation of Old Reviva in May 2006.

(4) Narayan Prabhu began serving as our Chief Financial Officer on December 14, 2020.

Employment Agreements

Laxminarayan Bhat. On December 14, 2020 we entered into a customary employment agreement with Dr. Bhat (the "Bhat Employment Agreement"). The Bhat Employment Agreement provides for Dr. Bhat to serve as Chief Executive Officer reporting to our board of directors and provides for an annual base salary of $400,000 (the "Base Salary"). In addition, Dr. Bhat is eligible to receive an annual bonus of up to fifty percent (50%) of his then-Base Salary (the "Target Bonus"), subject to the satisfaction of certain subjective or objective criteria established and approved by our compensation committee. Pursuant to the terms of the Bhat Employment Agreement, Dr. Bhat is eligible to receive equity awards under the Company's equity incentive plan. The Bhat Employment Agreement contains customary confidentiality and assignment of inventions provisions. In addition, we will indemnify and hold Dr. Bhat harmless, to the maximum extent permitted under applicable law, from and against any liabilities, costs, claims and expenses incurred in defense of any Proceeding (as defined in the Bhat Employment Agreement) that Dr. Bhat is made a party to.

If we terminate Dr. Bhat's employment without Cause or Dr. Bhat terminates his employment for Good Reason (each as defined in the Bhat Employment Agreement), Dr. Bhat will be entitled to receive (i) the Accrued Amounts (as defined in the Bhat Employment Agreement), and subject to Dr. Bhat's execution and nonrevocation of a release of claims, (ii) eighteen (18) months of his Base Salary plus one and one-half times his annual Target Bonus (reduced to six (6) months of Base Salary and one-half of his annual Target Bonus if Dr. Bhat's employment is terminated after the third anniversary of the effective date of the Bhat Employment Agreement) payable in equal installments in accordance with the Company's normal payroll practices, (iii) twelve (12) months of service credit under all outstanding unvested equity incentive awards granted during Dr. Bhat's employment (reduced to six (6) months of service credit if Dr. Bhat's employment is terminated after the third anniversary of the effective date of the Bhat Employment Agreement) and (iv) reimbursement of COBRA coverage for up to eighteen (18) months. If Dr. Bhat's employment is terminated on account of his death or Disability (as defined in the Bhat Employment Agreement), Dr. Bhat will be entitled to receive the Accrued Amounts and a lump sum payment equal to eighteen (18) months Base Salary and Target Bonus. In addition, if we terminate Dr. Bhat's employment without Cause or Dr. Bhat terminates his employment for Good Reason within twelve (12) months following a Change in Control (as defined in the Bhat Employment Agreement), Dr. Bhat will be entitled to receive (i) the Accrued Amounts and, subject to Dr. Bhat's execution and nonrevocation of a release of claims, (ii) a lump sum payment equal to 1.5 times his Base Salary and Target Bonus for the year in which the termination occurs, (iii) accelerated vesting of all of his outstanding equity incentive awards and cash incentive payments and (iv) reimbursement of COBRA coverage for up to eighteen (18) months.

Simultaneously with the execution of the Merger Agreement, Dr. Bhat entered into non-competition and non-solicitation agreement (the "Non-Competition Agreement"), which became effective on December 14, 2020, pursuant to which Dr. Bhat agreed not to compete with Tenzing, Reviva and their respective affiliates during the three (3) year period following the Closing in North America, Europe or India or in any other markets in which Tenzing and Reviva are engaged. Dr. Bhat also agreed that during such three (3) year restricted period to not solicit employees or customers of such entities. The Non-Competition Agreement also contains customary confidential and mutual non-disparagement provisions.

On February 8, 2023, our compensation committee (i) awarded Dr. Bhat a $160,000 bonus for 2022, representing 40% of his then-current base salary, (ii) set Dr. Bhat's new base salary for 2023 at $450,000, effective as of January 1, 2023, and (iii) determined that Dr. Bhat is eligible to receive a 2023 bonus at a target level of 50% of his then-current base salary, subject to the satisfaction of certain subjective and/or objective criteria established and approved by our compensation committee. On April 25, 2023, our compensation committee awarded Dr. Bhat an option to purchase 443,000 shares of our common stock at an exercise price of $6.74 per share, based on the closing price of our common stock on the grant date in accordance with the terms of our 2020 Equity Incentive Plan (the "2020 Plan"). The option was immediately vested as to 50% of the shares subject thereto on the grant date, and provides for vesting as to an additional 1.389% of the shares subject thereto on the last day of each month thereafter. On September 15, 2024, our compensation committee determined the amount of incentive bonus earned by Dr. Bhat for 2023 and awarded Dr. Bhat a bonus of $160,000, paid in the form of an immediately vested option to purchase 158,451 shares of our common stock at an exercise price of $1.20 per share, based on the closing price of our common stock on September 13, 2024, in accordance with the terms of the 2020 Plan.

On February 13, 2025, our compensation committee (i) approved an increase in Dr. Bhat's base salary to $565,000, effective retroactively to January 1, 2025; (ii) approved a cash bonus payment to Dr. Bhat in respect of fiscal year 2024 in an amount of $157,500; (iii) determined that Dr. Bhat is eligible to earn a discretionary bonus for fiscal year 2025 at a target level of 50% of base salary, subject to the satisfaction of certain subjective and/or objective criteria established and approved by our compensation committee; and (iv) granted Dr. Bhat an option to purchase 519,000 shares of our common stock at an exercise price of $1.80 per share, based on the closing price of our common stock on the grant date in accordance with the terms of the 2020 Plan, with such option award immediately vested as to approximately 42% of the shares subject thereto on the grant date, and providing for vesting as to the remainder of the shares subject thereto in specified monthly installments over the period from March 2025 through December 2027.

Narayan Prabhu. On December 14, 2020, an offer letter Reviva entered into with Narayan Prabhu, dated October 19, 2020, became effective (the "Prabhu Offer Letter"). The Prabhu Offer Letter provides for Mr. Prabhu to serve as Chief Financial Officer reporting to our Chief Executive Officer or our board of directors and provides for an annual base salary of $275,000. Pursuant to the Prabhu Offer Letter, Mr. Prabhu's employment with the Company will be at-will.

In addition, Mr. Prabhu is eligible for a discretionary bonus. Pursuant to the Prabhu Offer Letter, subject to approval by the board of directors, Mr. Prabhu was granted a stock option to purchase up to fifty thousand (50,000) shares of our common stock pursuant to our Reviva Pharmaceuticals Holdings, Inc. 2020 Equity Incentive Plan (the "2020 Equity Incentive Plan") on April 14, 2021. Pursuant to the terms of the Prabhu Offer Letter, Mr. Prabhu is also eligible to receive, from time to time, equity awards under our 2020 Equity Incentive Plan, or any other equity incentive plan that we may adopt in the future, and the terms and conditions of such awards, if any, will be determined by our board of directors, or a committee thereof, in their discretion.

On February 8, 2023, our compensation committee (i) awarded Mr. Prabhu a $137,500 bonus for 2022, representing 50% of his then-current base salary (and taking into account that no bonus was paid to Mr. Prabhu for 2021), (ii) set Mr. Prabhu's new base salary for 2023 at $325,000, effective as of January 1, 2023, and (iii) determined that Mr. Prabhu is eligible to receive a 2023 bonus at a target level of 41% of his then-current base salary, subject to the satisfaction of certain subjective and/or objective criteria established and approved by our compensation committee. On April 25, 2023, our compensation committee awarded Mr. Prabhu an option to purchase 170,000 shares of our common stock at an exercise price of $6.74 per share, based on the closing price of our common stock on the grant date in accordance with the terms of our 2020 Equity Incentive Plan. The option was immediately vested as to 50% of the shares subject thereto on the grant date, and provides for vesting as to an additional 1.389% of the shares subject thereto on the last day of each month thereafter. On September 15, 2024, our compensation committee determined the amount of incentive bonus earned by Mr. Prabhu for 2023 and awarded Mr. Prabhu a bonus of $137,500, paid in the form of an immediately vested option to purchase 95,940 shares of our common stock at an exercise price of $1.20 per share, based on the closing price of our common stock on September 13, 2024, in accordance with the terms of the 2020 Plan.

On February 13, 2025, our compensation committee (i) approved an increase in Mr. Prabhu's base salary to $330,000, effective retroactively to January 1, 2025; (ii) approved a cash bonus payment to Mr. Prabhu in respect of fiscal year 2024 in an amount of $79,950; (iii) determined that Mr. Prabhu is eligible to earn a discretionary bonus for fiscal year 2025 at a target level of 41% of base salary, subject to the satisfaction of certain subjective and/or objective criteria established and approved by our compensation committee; and (iv) granted Mr. Prabhu an option to purchase 194,250 shares of our common stock at an exercise price of $1.80 per share, based on the closing price of our common stock on the grant date in accordance with the terms of the 2020 Plan, with such option award immediately vested as to approximately 42% of the shares subject thereto on the grant date, and providing for vesting as to the remainder of the shares subject thereto in specified monthly installments over the period from March 2025 through December 2027.

Outstanding Equity Awards at Fiscal Year-End — 2024

The following table summarizes, for each of the named executive officers, the number of shares of our common stock underlying outstanding stock options held as of December 31, 2024:

	Option Awards				
	Number of securities underlying unexercised options			Option exercise price ($)	Option expiration date
Name	Exercisable	Unexercisable			
Laxminarayan Bhat, PhD (CEO)	350,713	92,287	(1)	$ 6.74	April 24, 2033
	158,451	—	(2)	$ 1.20	September 14, 2034
Narayan Prabhu (CFO)	134,581	35,419	(1)	$ 6.74	April 24, 2033
	96,519	—	(2)	$ 1.20	September 14, 2034
	50,000	—	(3)	$ 4.30	April 13, 2031

(1) Represents options to purchase shares of our common stock granted on April 25, 2023 with an exercise price of $6.74 per share. The shares underlying the option vest starting April 25, 2023 with 50% vesting immediately on April 25, 2023, then 1.389% vesting on a monthly basis over the following 36 months from April 2023 to March 2026. The award was made pursuant to the 2020 Equity Incentive Plan.

(2) Represents options to purchase shares of our common stock granted on September 15, 2024 with an exercise price of $1.20 per share. The shares underlying the option vested immediately on September 15, 2024. The award was made pursuant to the 2020 Equity Incentive Plan.

(2) Represents options to purchase shares of our common stock granted on April 14, 2021 with an exercise price of $4.30 per share. The shares underlying the option vest starting December 2020 with 25% after a one-year cliff in December 2021, then 2.0833% vesting on a monthly basis over the following 36 months from January 2022 to December 2023. The award was made pursuant to the 2020 Equity Incentive Plan.

Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

We do not have any formal policy that requires us to grant, or avoid granting, stock options at particular times. Consistent with our annual compensation cycle, if options are to be granted, the Compensation Committee generally seeks to grant annual stock option awards in connection with their conducting and completing such annual review, which typically occurs in approximately the fourth quarter or first quarter of each year. Options are awarded to our non-employee directors pursuant to our Non-Employee Director Compensation Policy, as amended, which provides that each independent director is entitled to receive a one-time initial equity grant upon such director's initial election, and an annual equity grant which is awarded on the date of our annual meeting of stockholders. The timing of any stock option grants in connection with new hires, promotions, or other non-routine grants may be tied to the event giving rise to the award (such as an employee's commencement of employment or promotion effective date), and in other cases such grants may be awarded at the same time with other annual grants. As a result, in all cases, the timing of grants of stock options occurs independent of the release of any material nonpublic information, and we do not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

No stock options were issued to executive officers in 2024 during any period beginning four business days before the filing of a periodic report or current report disclosing material non-public information (other than a current report on Form 8-K disclosing a material new option award grant under Item 5.02(e) of that form) and ending one business day after the filing or furnishing of such report with the SEC.

Director Compensation

The following table sets forth information concerning the compensation paid to certain of our non-employee directors during 2024:

Name	Fees earned or paid in cash ($)	Stock awards ($)	Option awards ($) (1)	Non-equity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation ($)	Total ($)
Les Funtleyder	51,250	—	17,109(2)	—	—	—	68,359
Richard Margolin	45,000	—	17,109(3)	—	—	—	62,109
Purav Patel	53,750	—	17,109(4)	—	—	—	70,859
Parag Saxena	70,250	—	17,109(5)	—	—	—	87,359

(1) Amounts reflect the aggregate grant date fair value of each stock option granted in 2024 in accordance with the Accounting Standards Codification Topic 718. For information regarding assumptions underlying the valuation of equity awards, see Note 5 to our Consolidated Financial Statements included in this report. These amounts do not correspond to the actual value that may be received by the directors if the stock options are exercised.

(2) The aggregate number of shares of common stock underlying stock options outstanding as of December 31, 2024 held by Mr. Funtleyder were 29,600.

(3) The aggregate number of shares of common stock underlying stock options outstanding as of December 31, 2024 held by Dr. Margolin were 29,600.

(4) The aggregate number of shares of common stock underlying stock options outstanding as of December 31, 2024 held by Mr. Patel were 44,827.

(5) The aggregate number of shares of common stock underlying stock options outstanding as of December 31, 2024 held by Mr. Saxena were 29,600.

Non-Employee Director Compensation

On the recommendation of our compensation committee, on June 15, 2021, our board of directors approved a non-employee director compensation policy (the "Non-Employee Director Compensation Policy"). On February 10, 2023, our compensation committee approved certain amendments to equity compensation provisions of the policy (the "February 2023 Amendments"), providing that going forward the equity compensation component of the policy shall consist of equity grants of fixed quantities of shares in lieu of grants determined by reference to a dollar value of shares, as described below. The Non-Employee Director Compensation Policy provides for the following compensation:

The Non-Employee Director Compensation Policy provides for the following cash compensation. The cash compensation component of the Non-Employee Director Compensation Policy was unchanged by the February 2023 Amendments:

- Each non-employee director is entitled to receive an annual cash retainer fee of $32,500, except that the Chairman of the Board is entitled to receive an annual cash retainer fee of $57,500;
- Each non-employee director sitting on our audit committee is entitled to receive an annual cash retainer fee of $7,500, except that the Chairman of our audit committee is entitled to receive an annual cash retainer fee of $15,000;
- Each non-employee director sitting on our compensation committee is entitled to receive an annual cash retainer fee of $5,000, except that the Chairman of our compensation committee is entitled to receive an annual cash retainer fee of $10,000;
- Each non-employee director sitting on our nominating and corporate governance committee is entitled to receive an annual cash retainer fee of $3,750, except that the Chairman of our nominating and corporate governance committee is entitled to receive an annual cash retainer fee of $7,750; and
- No per meeting fees shall be paid.

All annual cash retainer fees under the Non-Employee Director Compensation Policy are paid quarterly in arrears.

The Non-Employee Director Compensation Policy also provides generally for certain equity compensation under the Company's existing 2020 Equity Incentive Plan, or any other equity incentive plan the Company may adopt in the future, as described below. Prior to the adoption of the February 2023 Amendments, the equity compensation under the Non-Employee Director Compensation Policy consisted of, and was paid in accordance with, the following:

- Each non-employee director was entitled to receive, upon initial election, a one-time initial equity grant of nonqualified stock options in respect of a whole number of shares of our common stock with an approximate value of $20,000. All of the shares subject to the initial equity grant shall vest 33% per year over three years from the date of initial election, provided that the recipient remains a director of through each vesting date.

- Each non-employee director was entitled to receive an annual equity grant of nonqualified stock options in respect of a whole number of shares of the our common stock with an approximate value of $20,000. All of the shares subject to the annual equity grant shall cliff vest after 1-year, provided that the recipient remains a director through the vesting date.

From and after the adoption of the February 2023 Amendments, the equity compensation under the Non-Employee Director Compensation Policy consists of, and is paid in accordance with, the following:

- Each non-employee director is entitled to receive, upon initial election, a one-time initial equity grant of nonqualified stock options in respect of 8,200 shares of our common stock. All of the shares subject to the initial equity grant shall vest 33% per year over three years from the date of initial election, provided that the recipient remains a director of through each vesting date.

- Each non-employee director is entitled to receive an annual equity grant of nonqualified stock options in respect of 8,200 shares of our common stock. All of the shares subject to the annual equity grant shall cliff vest after 1-year, provided that the recipient remains a director through such vesting date. Annual equity grants for directors who are initially elected in the 12 months following the most recent annual grant will be pro-rated on a monthly basis based on time of election as appropriate.

Indemnification Agreements

On December 14, 2020, our board of directors adopted and entered into (a) a form of indemnification agreement (the "Indemnification Agreement") between the Company and each of its directors and executive officers, except for Parag Saxena, and (b) a form of indemnification agreement (the "Saxena Indemnification Agreement") with Parag Saxena.

The Indemnification Agreement requires us to indemnify each director and officer to the fullest extent permitted by applicable law, for certain expenses, including attorneys' fees, judgments, penalties, fines and settlement amounts actually and reasonably incurred in any threatened, pending or completed action, suit, claim, investigation, inquiry, administrative hearing, arbitration or other proceeding to which the director or officer was, or is threatened to be made, a party by reason of the fact that such director or officer is or was a director, officer, employee or agent of us. Subject to certain limitations, the Indemnification Agreement provides for the advancement of expenses incurred by the indemnitee, and the repayment to us of the amounts advanced to the extent that it is ultimately determined that the indemnitee is not entitled to be indemnified by us. The Indemnification Agreement also creates certain rights in favor of us, including the right to assume the defense of claims and to consent to settlements. The Indemnification Agreement does not exclude any other rights to indemnification or advancement of expenses to which the indemnitee may be entitled under applicable law, the certificate of incorporation or our bylaws, any agreement, a vote of stockholders or disinterested directors, or otherwise.

The Saxena Indemnification Agreement is on substantially the same form as the Indemnification Agreement, except that it includes a provision specifying that the we will act as the indemnitor of first resort and that we will not assert that Mr. Saxena, as indemnitee under the Saxena Indemnification Agreement, must seek expense advancement or reimbursement, or indemnification, from any stockholder of the Company and/or certain of any such stockholder's affiliates who Mr. Saxena may have rights to indemnification, advancement of expenses and/or insurance from, before we must perform our expense advancement and reimbursement, and indemnification obligations, under the Saxena Indemnification Agreement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance Under Equity Compensation Plans

2020 Equity Incentive Plan

On December 14, 2020, the Reviva Pharmaceuticals Holdings, Inc. 2020 Equity Incentive Plan (the "2020 Equity Incentive Plan") became effective. The general purpose of the 2020 Equity Incentive Plan is to provide a means whereby employees, officers, directors, consultants, advisors or other individual service providers may develop a sense of proprietorship and personal involvement in our development and financial success, and to encourage them to devote their best efforts to us, thereby advancing our interests and the interests of our stockholders.

The following table provides information with respect to our compensation plans under which equity compensation was authorized as of December 31, 2024.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)(3)
Equity compensation plans approved by security holders (1)	2,559,440(2)	$ 4.07	2,800,506(4)
Equity compensation plans not approved by security holders	—	—	—
Total	2,559,440	$ 4.07	2,800,506

(1) The amounts shown in this row include securities under the Reviva Pharmaceuticals, Inc. 2006 Equity Incentive Plan (the "2006 Equity Incentive Plan") and the 2020 Equity Incentive Plan.

(2) Includes 0 and 2,559,440 shares of common stock issuable upon exercise of outstanding options pursuant to the 2006 Equity Incentive Plan and 2020 Equity Incentive Plan, respectively, as of December 31, 2024.

(3) In accordance with the "evergreen" provision in our 2020 Equity Incentive Plan, an additional 4,657,919 shares were automatically made available for issuance on the first day of 2025, which represents 10% of the number of shares of the Company's common stock outstanding on December 31, 2024; these shares are excluded from this calculation as such shares were not available for issuance under the 2020 Equity Incentive Plan at year-end 2024 and did not become so available until the first day of 2025.

(4) Includes 0 and 2,800,506 shares of common stock available for issuance under the 2006 Equity Incentive Plan and 2020 Equity Incentive Plan, respectively, as of December 31, 2024.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information regarding the beneficial ownership of the Company, on March 14, 2025, by:

- each person known by the Company to be, or expected to be, the beneficial owner of more than 5% of shares of the Company's Common Stock;
- each of the Company's named executive officers and directors; and
- all directors and current executive officers as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security, including options and warrants that are currently exercisable or exercisable within 60 days.

The beneficial ownership of the common stock of the Company is based on 46,739,949 shares of common stock issued and outstanding as of March 14, 2025.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Named Executive Officers and Directors (1)		
Laxminarayan Bhat (2)	3,543,890	7.41%
Les Funtleyder (3)	21,400	*
Richard Margolin (4)	21,400	*
Purav Patel (5)	96,659	*
Narayan Prabhu (6)	479,579	1.02%
Parag Saxena (7) (8)	6,267,906	12.36%
All Directors and Executive Officers as a Group (six persons)	**10,430,834**	20.79%
Greater than Five Percent Holders:		
Tang Capital Partners, L.P. (9)	3,339,975	6.67%
Armistice Capital, LLC (10)	3,357,953	6.70%

* Less than one percent.

(1) The business address of each of the officers and directors is c/o Reviva Pharmaceuticals Holdings, Inc., 10080 N. Wolfe Road, Suite SW3-200, Cupertino, CA 95014.

(2) Includes (a) 771,527 shares of common stock issuable upon the exercise of stock options held by Dr. Bhat that are exercisable or will be exercisable within 60 days of March 14, 2025, (b) 5,388 shares of common stock held by Dr. Bhat's spouse and (c) 288,119 shares of common stock issuable upon the exercise of options held by Dr. Bhat's spouse, that are exercisable or will be exercisable within 60 days of March 14, 2025. Does not include 348,924 shares of our common stock issuable upon the exercise of stock options held by Dr. Bhat that are not exercisable within sixty days of March 14, 2025, and 121,224 shares of our common stock issuable upon the exercise of stock options held by Dr. Bhat's spouse that are not exercisable within sixty days of March 14, 2025.

(3) Includes 21,400 shares of common stock issuable upon the exercise of stock options that are exercisable or will be exercisable within 60 days of March 14, 2025. Does not include 8,200 shares of our common stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 14, 2025.

(4) Includes 21,400 shares of common stock issuable upon the exercise of stock options that are exercisable or will be exercisable within 60 days of March 14, 2025. Does not include 8,200 shares of our common stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 14, 2025.

(5) Includes 36,627 shares of common stock issuable upon the exercise of stock options that are exercisable or will be exercisable within 60 days of March 14, 2025. Does not include 8,200 shares of our common stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 14, 2025.

(6) Includes 379,579 shares of common stock issuable upon the exercise of stock options that are exercisable or will be exercisable within 60 days of March 14, 2025. Does not include 131,190 shares of our common stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 14, 2025.

(7) Based on the information provided in the Schedule 13D filed with the SEC on January 31, 2025, by Mr. Saxena with respect to himself, Vedanta Associates, L.P., Beta Operators Fund, L.P., Vedanta Associates-R, L.P. and Vedanta Partners, LLC. Includes (a) 99,539 shares held by Vedanta Associates, L.P. (b) 399,000 shares held by Beta Operators Fund, L.P., (c) 931,000 shares held by Vedanta Associates-R, L.P., (d) 869,565 shares of common stock issuable upon the exercise of pre-funded warrants held by Beta Operators Fund, L.P., (e) 513,834 shares of common stock issuable upon the exercise of pre-funded warrants held by Vedanta Associates-R, L.P., (f) 585,366 shares of common stock issuable upon exercise of pre-funded warrants held by Vedanta R2 Partners, LP ("Vedanta R2"), (g) 869,565 shares of shares of common stock issuable upon the exercise of warrants held by Beta Operators Fund, L.P., (h) 521,934 shares of common stock issuable upon the exercise of warrants held by Vedanta Associates-R, L.P., (i) 585,366 shares of common stock issuable upon exercise of warrants held by Vedanta R2, and (j) 21,400 shares of common stock issuable upon the exercise of stock options held by Mr. Saxena that are exercisable or will be exercisable within 60 days of March 14, 2025. Vedanta Partners, LLC is the general partner of Vedanta Associates, L.P. and Vedanta Associates-R, L.P. Vedanta Associates, L.P. is the general partner of Beta Operators Fund, L.P. and Vedanta R2. Vedanta Partners, LLC has voting and dispositive power over the securities held by Vedanta Associates, L.P. and Vedanta Associates-R, L.P. Vedanta Associates, L.P. has voting and dispositive power over securities held by Beta Operators Fund L.P. and Vedanta R2. Parag Saxena is the majority member of Vedanta Partners, LLC and controls Vedanta Partners, LLC, Vedanta Associates-R, L.P., Beta Operators Fund, L.P. and Vedanta R2, and may be deemed to be the beneficial owner of such securities. Mr. Saxena, however, disclaims beneficial ownership over any securities owned by Vedanta Associates, L.P., Vedanta Associates-R, L.P., Beta Operators Fund, L.P. and Vedanta R2 in which he does not have any pecuniary interest. Does not include (a) 299,250 shares of common stock issuable upon the exercise of 399,000 warrants held by Beta Operators Fund, L.P. which are subject to a 4.99% beneficial ownership limitation blocker, (b) 689,150 shares of common stock issuable upon the exercise of 918,867 warrants held by Vedanta Associates-R, L.P. which are subject to a 4.99% beneficial ownership limitation blocker, or (c) 8,200 shares of common stock issuable upon the exercise of stock options held by Mr. Saxena that are not exercisable within 60 days of March 14, 2025.

(8) The business address of Vedanta Associates, L.P., Beta Operators Fund, L.P., Vedanta Associates-R, L.P. and Vedanta Partners, LLC is c/o Vedanta Partners, LLC, 250 West 55th Street, New York, New York 10019.

(9) Based on the information provided in the Schedule 13G/A filed with the SEC on February 14, 2024 by Tang Capital Partners, L.P. with respect to itself, Tang Capital Management, LLC and Kevin Tang. Includes 3,339,975 shares of common stock issuable upon the exercise of warrants held by Tang Capital Partners, L.P. The exercise of the warrants are subject to a 9.99% beneficial ownership limitation blocker which the holder has elected. Tang Capital Management, LLC is the general partner of Tang Capital Partners, L.P. and has voting and dispositive power over the securities held by Tang Capital Partners, L.P. Kevin Tang is the manager of Tang Capital Management, LLC. The address for Tang Capital Partners, L.P., Tang Capital Management, LLC and Kevin Tang is 4747 Executive Drive, Suite 210, San Diego, CA 92121.

(10) Based on the information provided in the Schedule 13G/A filed with the SEC on November 14, 2024 by Armistice Capital, LLC ("Armistice") with respect to itself and Steven Boyd. Includes 3,357,953 shares of common stock beneficially owned by Armistice, the investment manager of Armistice Capital Master Fund Ltd. (the "Master Fund"), the direct holder of such shares. Pursuant to an Investment Management Agreement, Armistice exercises voting and investment power over the shares held by the Master Fund and thus may be deemed to beneficially own such shares. Mr. Boyd, as the managing member of Armistice, may be deemed to beneficially own the shares held by the Master Fund. The Master Fund specifically disclaims beneficial ownership of the securities of the Company directly held by it by virtue of its inability to vote or dispose of such securities as a result of its Investment Management Agreement with Armistice. The address for Armistice and Steven Boyd is 510 Madison Avenue, 7th Floor, New York, New York, 10022. Does not include the following securities purchased by Armistice in the December 2024 Underwritten Offering: (i) 2,666,668 shares of common stock, (ii) 1,333,334 shares underlying Series A Common Warrants which are subject to a 4.99% blocker, and (iii) 2,666,668 shares underlying Series B Common Warrants which are subject to a 4.99% blocker.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The following includes a summary of transactions since January 1, 2023, to which we or Tenzing have been a participant in which the amount involved exceeded or will exceed the lesser of (i) $120,000 or (ii) 1% of our average total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described in the section entitled "*Executive Compensation*."

Indian Subsidiary

Mr. Krishnamurthy Bhat, an Indian resident and the brother of Dr. Bhat, the Company's Chief Executive Officer, holds a 1% ownership stake and is a director of the Company's subsidiary, Reviva Pharmaceuticals India Private Limited. The Indian government regulates ownership of Indian companies by non-residents. Foreign investment in Indian securities is generally regulated by the Consolidated Policy on Foreign Direct Investment issued by the Government and the Foreign Exchange Management Act, 1999, which prevents 100% ownership by a foreign parent company of its Indian subsidiary.

Employment

Reviva employs Seema R. Bhat, the spouse of Laxminarayan Bhat, the Company's Chief Executive Officer, as its Vice President for Program & Portfolio Management, pursuant to an Offer Letter dated March 1, 2011 (the "Bhat 2011 Offer Letter"). In October 2015, Ms. Bhat entered into a letter agreement with Old Reviva pursuant to which Ms. Bhat agreed to a reduction in her base annual salary to $30,000 for an indefinite period of time. Effective since October 2018, Ms. Bhat had agreed to defer her entire salary, without interest. Effective as of October 2, 2020, 35,385 shares of Old Reviva common stock were issued to Ms. Bhat in full satisfaction of the entire deferred salary balance owed to Ms. Bhat, pursuant to a Stock Issuance Agreement and Release.

On June 16, 2021, the Company entered into an Employment Letter with Ms. Bhat (the "Bhat 2021 Employment Letter"), which supersedes the Bhat 2011 Offer Letter. The Bhat 2021 Employment Letter provides for Ms. Bhat to continue to serve as our Vice President for Program & Portfolio Management reporting to our Chief Executive Officer or our Board and provides for an annual base salary of $277,000, retroactive to December 15, 2020 (the day following the Business Combination). Under the Bhat 2021 Employment Letter, Ms. Bhat is eligible for annual bonuses in the discretion of our Board. The Bhat 2021 Employment Letter provides that to receive any bonus, Ms. Bhat must be employed by the Company at the time of payment. The Bhat 2021 Employment Letter provides that Ms. Bhat may also receive, in the discretion of our Board, equity awards under the Company's 2020 Equity Incentive Plan or any other equity incentive plan that the Company may adopt in the future. The Bhat 2021 Employment Letter contains customary confidentiality and assignment of inventions provisions. On February 8, 2023, our compensation committee (i) awarded Ms. Bhat a $83,100 bonus for 2022, representing 30% of her then-current base salary, (ii) set Ms. Bhat's new base salary for 2023 at $310,000, effective as of January 1, 2023, and (iii) determined that Ms. Bhat is eligible to receive a 2023 bonus at a target level of 32% of her then-current base salary, subject to the satisfaction of certain subjective and/or objective criteria established and approved by our compensation committee. On April 25, 2023, our compensation committee awarded Ms. Bhat an option to purchase 150,000 shares of our common stock at an exercise price of $6.74 per share, based on the closing price of our common stock on the grant date in accordance with the terms of our 2020 Plan. The option was immediately vested as to 50% of the shares subject thereto on the grant date, and provides for vesting as to an additional 1.389% of the shares subject thereto on the last day of each month thereafter. On September 15, 2024, our compensation committee determined the amount of incentive bonus earned by Ms. Bhat for 2023 and awarded Ms. Bhat a bonus of $77,376, paid in the form of an immediately vested stock option to purchase

77,843 shares of our common stock at an exercise price of $1.20 per share, based on the closing price of our common stock on September 13, 2024, in accordance with the terms of the 2020 Plan.

On February 13, 2025, our compensation committee (i) approved an increase in Ms. Bhat's base salary to $340,000, effective retroactively to January 1, 2025; (ii) approved a cash bonus payment to Ms. Bhat in respect of fiscal year 2024 in an amount of $77,500; (iii) determined that Ms. Bhat is eligible to earn a discretionary bonus for fiscal year 2025 at a target level of 32% of base salary, subject to the satisfaction of certain subjective and/or objective criteria established and approved by our compensation committee; and (iv) granted Ms. Bhat an option to purchase 181,500 shares of our common stock at an exercise price of $1.80 per share, based on the closing price of our common stock on the grant date in accordance with the terms of the 2020 Plan, with such option award immediately vested as to approximately 42% of the shares subject thereto on the grant date, and providing for vesting as to the remainder of the shares subject thereto in specified monthly installments over the period from March 2025 through December 2027.

Effective since April 2019, Dr. Bhat had agreed to the deferral of past salary as necessary, without interest. Effective as of October 2, 2020, 132,506 shares of Old Reviva common stock were issued to Dr. Bhat in full satisfaction of the entire deferred salary balance owed to Dr. Bhat, pursuant to a Stock Issuance Agreement and Release.

Participation in 2023 Offering

Vedanta R2 Partners, LP ("Vedanta R2"), an investment vehicle managed by certain affiliates of Parag Saxena, the Chairman of our board of directors, of which Vedanta Associates, LP is the general partner, purchased an aggregate of approximately $3.0 million in pre-funded warrants and common warrants in a registered direct offering which was completed in November 2023. The placement agent received the same commission on the securities purchased by Vedanta R2 as they did from any other securities sold to other investors in the offering.

Indemnification Agreements

The Company has entered into indemnification agreements with each of its directors and named executive officers. These agreements require the Company to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to the Company, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. The Company also intends to enter into indemnification agreements with its future directors and executive officers. For a more fulsome description of the indemnification agreements refer to the disclosure in "*Executive Compensation*".

Policies and Procedures for Related Party Transactions:

Our board of directors has adopted a written policy, available on our website, which provides that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock, any members of the immediate family of any of the foregoing persons and any firms, corporations or other entities in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person has a 5% or greater beneficial ownership interest (collectively "related parties"), are not permitted to enter into a transaction with the Company without the prior consent of our board of directors acting through our audit committee or, in certain circumstances, the chairman of our audit committee. Any request for the Company to enter into a transaction with a related party, in which the amount involved exceeds $100,000 and such related party would have a direct or indirect interest must first be presented to our audit committee, or in certain circumstances the chairman of our audit committee, for review, consideration and approval. In approving or rejecting any such proposal, our audit committee, or the chairman of our audit committee, is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third-party under the same or similar circumstances, the extent of the benefits to us, the availability of other sources of comparable products or services and the extent of the related party's interest in the transaction.

Director Independence

Our board of directors undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that Mr. Saxena, Mr. Funtleyder, Dr. Margolin, and Mr. Patel do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Rules of the Nasdaq Market and the SEC.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to the Company's Principal Independent Registered Public Accounting Firm for Fiscal Years 2024 and 2023

The following table summarizes the fees for professional services provided by Moss Adams LLP ("Moss Adams"), our principal accountant, for audit services provided for, and other services provided in, the years ended December 31, 2024 and December 31, 2023:

	Year ended December 31, 2024	Year ended December 31, 2023
Audit Fees(1)	$ 822,568	$ 327,256
Audit-Related Fees	—	—
All Other Fees	—	—
Total	$ 822,568	$ 327,256

(1) Audit fees consist of fees incurred for professional services rendered for the audit of our annual financial statements and review of the quarterly financial statements, assistance with registration statements filed with the SEC, and services that are normally provided by our principal independent registered public accounting firm in connection with regulatory filings or engagements.

The following table summarizes the fees for professional services provided by Armanino LLP ("Armanino"), our previous principal accountant, for audit services provided for, and other services provided in, the year ended December 31, 2023:

	Year ended December 31, 2024	Year ended December 31, 2023
Audit Fees(1)	$ 91,903	$ 115,178
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total	$ 91,903	$ 115,178

(1) Audit fees consist of fees incurred for professional services rendered for the audit of our annual financial statements and review of the quarterly financial statements, assistance with registration statements filed with the SEC, and services that are normally provided by our previous principal independent registered public accounting firm in connection with regulatory filings or engagements.

Auditor Independence

In our fiscal year ended December 31, 2024, there were no other professional services provided by Moss Adams that would have required our audit committee to consider their compatibility with maintaining the independence of Moss Adams.

Audit Committee Policy on Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

Our audit committee has established a policy governing our use of the services of our independent registered public accounting firm. Under this policy, our audit committee is required to pre-approve all audit and non-audit services performed by our independent registered public accounting firm in order to ensure that the provision of such services does not impair the public accountants' independence. All fees paid to Moss Adams, for our fiscal years ended December 31, 2024 and December 31, 2023, and to Armanino, for our fiscal year ended December 31, 2023, were pre-approved by our audit committee.

Part IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The financial statements and related notes, together with the report of Moss Adams LLP appears at pages F-2 through F-25 following the Exhibit List as required by "Part II—Item 8—Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules

All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

(a)(3) EXHIBITS

The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

Exhibit No.	Exhibit
2.1+	Agreement and Plan of Merger, dated as of July 20, 2020, by and among the Company, Merger Sub, Sponsor in the capacity as the Purchaser Representative, Reviva, and Dr. Bhat in the capacity as the Seller Representative (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K as filed on July 24, 2020, and incorporated herein by reference).
3.1	Certificate of Corporate Domestication (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).
3.2	Interim Certificate of Incorporation (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K as filed on December 14, 2020, and incorporated herein by reference).
3.3	Amended and Restated Certificate of Incorporation (filed as Exhibit 3.3 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).
3.4	Certificate of Amendment to Certificate of Incorporation (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K as filed on December 12, 2024, and incorporated herein by reference).
3.5	Bylaws of Reviva Pharmaceuticals Holdings, Inc. (filed as Exhibit 3.2 to the Company's Current Report on Form 8-K as filed on December 14, 2020, and incorporated herein by reference).
4.1*	Description of Securities.
4.2	Form of Assumed Warrant (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).
4.3	Specimen Warrant Certificate (filed as Exhibit 4.3 to the Company's Form S-1 (File No. 333-226263) as filed on August 16, 2018, and incorporated herein by reference).
4.4	Warrant Agreement, dated August 20, 2018, between the Company and Continental Stock Transfer & Trust Company (filed as Exhibit 4.1 to the Company's Form 8-K as filed on August 24, 2018, and incorporated herein by reference).
4.5	Specimen common stock certificate of the Company (filed as Exhibit 4.4 to the Company's Form S-4 (File No. (333-245057) as filed on November 3, 2020, and incorporated herein by reference).
4.6	Form of Common Stock Purchase Warrant (filed as Exhibit 4.1 to the Company's Form 10-Q as filed on August 16, 2021, and incorporated herein by reference).
4.7	Form of Pre-Funded Common Stock Purchase Warrant (filed as Exhibit 4.2 to the Company's Form 10-Q as filed on August 16, 2021, and incorporated herein by reference).
4.8	Warrant Agency Agreement, dated June 1, 2021, between the Company and Continental Stock Transfer & Trust Company (filed as Exhibit 4.3 to the Company's Form 10-Q as filed on August 16, 2021, and incorporated herein by reference).
4.9	Form of Private Pre-Funded Warrant (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K as filed on September 7, 2022, and incorporated herein by reference).

4.10 Form of Private Placement Warrant (filed as Exhibit 4.2 to the Company's Current Report on Form 8-K as filed on September 7, 2022, and incorporated here by reference).

4.11 Form of Pre-Funded Warrant (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K as filed on November 17, 2023, and incorporated herein by reference).

4.12 Form of Common Warrant (filed as Exhibit 4.2 to the Company's Current Report on Form 8-K as filed on November 17, 2023, and incorporated herein by reference).

4.13 Form of Common Warrant from May 2024 Offering (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on May 29, 2024).

4.14 Form of Warrant Amendment Agreement from May 2024 Offering (incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on May 29, 2024)

4.15 Form of Warrant from August 2024 Offering (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on August 20, 2024).

4.16 Form of Pre-Funded Warrant from August 2024 Offering (incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on August 20, 2024).

4.17 Form of Underwriter Warrant from August 2024 Offering (incorporated by reference from Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on August 20, 2024).

4.18 Form of Warrant Amendment Agreement from August 2024 Offering (incorporated by reference from Exhibit 4.4 to the Company's Current Report on Form 8-K filed with the SEC on August 20, 2024).

4.19 Form of Series A Common Stock Warrant (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on December 18, 2024).

4.20 Form of Series B Common Stock Warrant (incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on December 18, 2024).

10.1# Employment Agreement, dated as of December 14, 2020, by and between the Company and Dr. Bhat. (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).

10.2 Form of Lock-Up Agreement (General) (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K as filed on July 24, 2020, and incorporated herein by reference).

10.3 Lock-Up Agreement, dated as of July 20, 2020, by and among Dr. Bhat, Tenzing and the Purchaser Representative (filed as Exhibit 10.3 to the Company's Current Report on Form 8-K as filed on July 24, 2020, and incorporated herein by reference).

10.4	Non-Competition Agreement, dated as of July 20, 2020, by Dr. Bhat in favor of Tenzing, Reviva and their respective affiliates (filed as Exhibit 10.4 to the Company's Current Report on Form 8-K as filed on July 24, 2020, and incorporated herein by reference).
10.5++#	Offer of Employment, dated as of October 19, 2020, by and between Narayan Prabhu and Reviva Pharmaceuticals, Inc. (filed as Exhibit 10.16 to the Company's Form S-4 (File No. (333-245057) as filed on November 6, 2020, and incorporated herein by reference).
10.6#	Form of Indemnification Agreement (filed as Exhibit 10.9 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).
10.7#	Saxena Indemnification Agreement (filed as Exhibit 10.10 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).
10.8	Form of Non-Redemption Agreement, dated as of December 8, 2020, by and among the Company, Tenzing LLC and the shareholder party thereto (filed as Exhibit 10.11 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).
10.9	Form of Registration Rights Agreement, dated as of December 14, 2020, by and between the Company and the shareholder party thereto (filed as Exhibit 10.12 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).
10.10#	Reviva Pharmaceuticals Holdings, Inc. 2020 Equity Incentive Plan (filed as Exhibit 10.13 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).
10.11#	Form of Incentive Stock Option Grant Agreement (filed as Exhibit 10.14 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).
10.12#	Form of Nonqualified Stock Option Grant Agreement (filed as Exhibit 10.15 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).
10.13#	Reviva Pharmaceuticals, Inc. 2006 Equity Incentive Plan (filed as Exhibit 10.16 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).
10.14#	First Amendment to Reviva Pharmaceuticals, Inc. 2006 Equity Incentive Plan (filed as Exhibit 10.17 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).
10.15#	Form of Assumed Option (filed as Exhibit 10.18 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).
10.16	Form of Note Purchase Agreement, dated as of August 27, 2020, by and between the Company and the investors party thereto (filed as Exhibit 10.19 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).

10.17 Form of Note Purchase Agreement, dated as of August 29, 2020, by and between the Company and the investors party thereto (filed as Exhibit 10.20 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).

10.18 Letter Agreement, dated as of December 14, 2020, by and between the Company, Maxim Group LLC and Maxim Partners LLC (filed as Exhibit 10.21 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).

10.19 Letter Agreement, dated August 20, 2018, by and among the Company, its officers, its directors and the Sponsor (filed as Exhibit 10.3 to the Company's Form 8-K filed on August 24, 2018, and incorporated herein by reference).

10.20 Registration Rights Agreement, dated as of August 20, 2018, by and among Tenzing, the Sponsor, Maxim and the holders party thereto (filed as Exhibit 10.2 to the Company's Form 8-K filed on August 24, 2018, and incorporated herein by reference).

10.21 Escrow Agreement, dated as of December 14, 2020, by and among the Company, Tenzing LLC, Laxminarayan Bhat and Continental Stock Transfer & Trust Company (filed as Exhibit 10.24 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).

10.22 Form of Backstop Agreement, by and among Tenzing Acquisition Corp., Reviva Pharmaceuticals, Inc., and the Investor named therein (filed as exhibit 10.1 to the Company's Form 8-K filed on October 21, 2020, and incorporated herein by reference).

10.23 Letter Agreement, dated August 20, 2018, by and among Tenzing, its officers, its directors and the Sponsor (incorporated by reference to Exhibit 10.3 of Tenzing's Form 8-K (File No. 001-38634), filed with the SEC on August 24, 2018).

10.24 Investment Management Trust Agreement, dated August 20, 2018, by and between Tenzing and Continental Stock Transfer & Trust Company, as trustee (incorporated by reference to Exhibit 10.1 of Tenzing's Form 8-K (File No. 001-38634), filed with the SEC on August 24, 2018).

10.25 Securities Purchase Agreement between Tenzing and Tenzing LLC (incorporated by reference to Exhibit 10.4 of Tenzing's Form S-1 (File No. 333-226263), filed with the SEC on July 20, 2018).

10.26 Form of Amended and Restated Unit Purchase Agreement between Tenzing and the Sponsor (incorporated by reference to Exhibit 10.4 of Tenzing's Form S-1 (File No. 333-226263), filed with the SEC on August 16, 2018).

10.27 Form of Unit Purchase Agreement between Tenzing and Maxim Group LLC (incorporated by reference to Exhibit 10.7 of Tenzing's Form S-1 (File No. 333-226263), filed with the SEC on August 16, 2018).

10.28 Promissory Note, dated February 10, 2020, issued by Tenzing Acquisition Corp. to Tenzing LLC (filed as exhibit 10.1 to the Company's Form 8-K filed on February 14, 2020, and incorporated herein by reference).

10.29 Promissory Note, dated May 21, 2020, issued by Tenzing Acquisition Corp. to Tenzing LLC (filed as exhibit 10.1 to the Company's Form 8-K filed on May 21, 2020, and incorporated herein by reference).

10.30 Promissory Note, dated July 24, 2020, issued by Tenzing Acquisition Corp. to Tenzing LLC (filed as exhibit 10.1 to the Company's Form 8-K filed on July 29, 2020, and incorporated herein by reference).

10.31 Promissory Note, dated August 18, 2020, issued by Tenzing Acquisition Corp. to Tenzing LLC (filed as exhibit 10.1 to the Company's Form 8-K filed on August 18, 2020, and incorporated herein by reference).

10.32 Promissory Note, dated September 24, 2020, issued by Tenzing Acquisition Corp. to Tenzing LLC (filed as exhibit 10.1 to the Company's Form 8-K filed on September 25, 2020, and incorporated herein by reference).

10.33 Promissory Note, dated November 12, 2020, issued by Tenzing Acquisition Corp. to Tenzing LLC (filed as exhibit 10.1 to the Company's Form 8-K filed on November 13, 2020, and incorporated herein by reference).

10.34 Form of Securities Purchase Agreement, dated September 6, 2022, by and between the Company and the Institutional Investor (filed as exhibit 10.1 to the Company's Form 8-K filed on September 7, 2022, and incorporated herein by reference).

10.35 Form of Securities Purchase Agreement, dated September 6, 2022, by and between the Company and the Private Placement Entities (filed as exhibit 10.2 to the Company's Form 8-K filed on September 7, 2022, and incorporated herein by reference).

10.36 Placement Agency Agreement, dated September 6, 2022, by and between the Company and the Placement Agent (filed as exhibit 10.3 to the Company's Form 8-K filed on September 7, 2022, and incorporated herein by reference).

10.37 Form of Securities Purchase Agreement, dated November 15, 2023, by and between the Company and the Purchasers (filed as Exhibit 10.1 to the Company's Form 8-K filed on November 17, 2023, and incorporated herein by reference).

10.38 Form of Securities Purchase Agreement from May 2024 Offering (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 29, 2024).

16.1 Letter of Armanino LLP to the Securities and Exchange Commission, dated October 4, 2023 (filed as Exhibit 16.1 to the Company's Form 8-K filed on October 4, 2023, and incorporated herein by reference).

16.2 Letter of Armanino LLP to the Securities and Exchange Commission, dated November 14, 2023 (filed as Exhibit 16.1 to the Company's Form 8-K/A filed on November 14, 2023, and incorporated herein by reference).

19.1*	Reviva Pharmaceuticals Holdings, Inc. Statement of Company Policy on Insider Trading and Policy Regarding Special Trading Procedures
21.1	List of Subsidiaries of the Company (filed as Exhibit 21.1 to the Company's Current Report on Form 8-K as filed on December 18, 2020 and incorporated herein by reference).
23.1*	Consent of Moss Adams LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included on the signature page).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)
32.1**	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350
97.1#	Reviva Pharmaceuticals Holdings, Inc. Compensation Recovery Policy (filed as Exhibit 97.1 to the Company's Annual Report on Form 10-K filed on April 15, 2024, and incorporated herein by reference).
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.

\+ The exhibits and schedules to this Exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The registrant hereby agrees to furnish a copy of any omitted schedules to the Commission upon request.

++ Certain information in this exhibit has been omitted pursuant to Item 601(a)(6) of Regulation S-K.

\# Indicates management contract or compensatory plan.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Reviva Pharmaceuticals Holdings, Inc.
(Registrant)

Date: April 2, 2025

By: /s/ Laxminarayan Bhat
Laxminarayan Bhat
Chief Executive Officer
(Principal Executive Officer)

Date: April 2, 2025

By: /s/ Narayan Prabhu
Narayan Prabhu
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Laxminarayan Bhat and Narayan Prabhu, jointly and severally, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him, and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Laxminarayan Bhat Laxminarayan Bhat	Chief Executive Officer and Director (Principal Executive Officer)	April 2, 2025
/s/ Narayan Prabhu Narayan Prabhu	Chief Financial Officer (Principal Financial and Accounting Officer)	April 2, 2025
/s/ Parag Saxena Parag Saxena	Chairman of the Board	April 2, 2025
/s/ Richard Margolin Richard Margolin	Director	April 2, 2025
/s/ Purav Patel Purav Patel	Director	April 2, 2025
/s/ Les Funtleyder Les Funtleyder	Director	April 2, 2025

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of
Reviva Pharmaceuticals Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Reviva Pharmaceuticals Holdings, Inc. (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2024 and 2023, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2 The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures to respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued Clinical Expenses

As described in Note 2 to the consolidated financial statements, the Company enters into contracts with contract research organizations to conduct clinical services on their behalf. The Company records costs relating to clinical services as they are incurred. The Company records accruals for estimated ongoing research and development costs. The Company determines the amount accrued each period end by reviewing purchase orders, open contracts, reports from the Company's contract research organization, reconciling payments and invoices and communicating with the Company's personnel and suppliers to identify services that have been performed on the Company's behalf. As necessary, the Company also obtains milestone and percentage completion reports from vendors and will estimate the level of service performed and the associated cost incurred for the services when it has not yet been invoiced or otherwise notified of the actual cost, which requires management judgment in estimating such amounts. The amount accrued for clinical expenses was $6.7 million as of December 31, 2024.

We identified the auditing of the estimate for accrued clinical expenses as of December 31, 2024, as a critical audit matter. The Company's determination of the accounting estimates included in the accrual for clinical trial costs requires management judgment, which in turn led to especially challenging and subjective auditor judgment.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. Our audit procedures related to the matter included the following, among others:

- Testing management's process for determining the estimate for accrued clinical expenses, including:
  - Obtaining an understanding of the terms and conditions included in the contract research organization contracts and related site agreements.
  - Evaluating management's methodology to estimate the amounts incurred for clinical services.
  - Evaluating the reasonableness of the significant assumptions used by management including estimated budget, estimated unreported costs based on historical trending of reported costs to date, and projected costs remaining until the conclusion of the trials, including, but not limited to the following:
    - Performing inquiries with both the Company's contract research organization and the Company's operations personnel overseeing the clinical trials to corroborate management's assumptions regarding the progress and status of the Company's clinical trial.
    - Confirming actual costs incurred and estimated budget directly from the Company's contract research organization.
    - Evaluating the sensitivity of changes to the significant assumptions.
  - Testing the completeness, accuracy, and relevance of the underlying data from the Company's contract research organization reports used by management.
  - Testing the mathematical accuracy of the calculations used in the estimate.

/s/ Moss Adams LLP

San Francisco, California
April 2, 2025

We have served as the Company's auditor since 2023.

REVIVA PHARMACEUTICALS HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 13,476,331	$ 23,367,456
Prepaid clinical trial costs	540,601	78,295
Prepaid expenses and other current assets	666,435	254,637
Total current assets	14,683,367	23,700,388
Non-current prepaid clinical trial costs	819,721	—
Total Assets	$ 15,503,088	$ 23,700,388
Liabilities and Stockholders' Equity		
Liabilities		
Short-term debt	$ 458,154	$ —
Accounts payable	6,283,430	3,849,108
Accrued clinical expenses	6,723,719	11,966,812
Accrued compensation	635,587	958,607
Other accrued liabilities	500,616	400,490
Total current liabilities	14,601,506	17,175,017
Warrant liabilities	89,010	806,655
Total Liabilities	14,690,516	17,981,672
Commitments and contingencies (Note 6)		
Stockholders' Equity		
Common stock, par value of $0.0001; 315,000,000 shares authorized; 46,579,199 and 27,918,560 shares issued and outstanding as of December 31, 2024 and 2023, respectively	4,658	2,792
Preferred Stock, par value of $0.0001; 10,000,000 shares authorized; 0 shares issued and outstanding as of December 31, 2024 and 2023	—	—
Additional paid-in capital	165,080,964	140,070,172
Accumulated deficit	(164,273,050)	(134,354,248)
Total stockholders' equity	812,572	5,718,716
Total Liabilities and Stockholders' Equity	$ 15,503,088	$ 23,700,388

The accompanying notes are an integral part of these consolidated financial statements.

REVIVA PHARMACEUTICALS HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2024	**2023**
Operating expenses		
Research and development	$ 22,907,368	$ 31,419,817
General and administrative	7,891,521	8,083,819
Total operating expenses	30,798,889	39,503,636
Loss from operations	(30,798,889)	(39,503,636)
Other income (expense)		
Gain (loss) on remeasurement of warrant liabilities	717,645	(239,216)
Interest expense	(18,497)	(33,725)
Interest income	361,369	398,413
Other (expense) income, net	(160,916)	134,276
Total other income, net	899,601	259,748
Loss before provision for income taxes	(29,899,288)	(39,243,888)
Provision for income taxes	19,514	16,949
Net loss	$ (29,918,802)	$ (39,260,837)
Net loss per share:		
Basic and diluted	$ (0.90)	$ (1.65)
Weighted average shares outstanding		
Basic and diluted	33,147,424	23,798,203

The accompanying notes are an integral part of these consolidated financial statements.

REVIVA PHARMACEUTICALS HOLDINGS, INC.

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2023	27,918,560	$ 2,792	$140,070,172	$(134,354,248)	$ 5,718,716
Common stock issued in connection with prefunded warrant exercises	1,485,643	149	—	—	149
Issuance of common stock in offering, net of transaction costs	17,174,996	1,717	10,918,984	—	10,920,702
Issuance of common stock warrants in offering, net of transaction costs	—	—	10,421,225	—	10,421,225
Issuance of prefunded warrants in offering, net of transaction costs	—	—	470,057	—	470,057
Issuance of underwriter warrants in offering	—	—	165,952	—	165,952
Modification of existing warrants, net of transaction costs	—	—	1,073,416	—	1,073,416
Stock-based compensation expense	—	—	1,630,341	—	1,630,341
Settlement of bonuses in form of stock options	—	—	330,816	—	330,816
Net loss	—	—	—	(29,918,802)	(29,918,802)
Balance at December 31, 2024	46,579,199	$ 4,658	$165,080,964	$(164,273,050)	$ 812,572

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2022 (As restated)	20,447,371	$ 2,045	$103,485,612	$ (95,093,411)	$ 8,394,246
Common stock issued in connection with warrant exercises	2,202,895	220	5,677,630	—	5,677,850
Issuance of common stock and warrants in offering, net of transaction costs	5,268,294	527	27,493,576	—	27,494,103
Stock-based compensation expense	—	—	3,413,354	—	3,413,354
Net loss	—	—	—	(39,260,837)	(39,260,837)
Balance at December 31, 2023	27,918,560	$ 2,792	$140,070,172	$(134,354,248)	$ 5,718,716

The accompanying notes are an integral part of these consolidated financial statements.

REVIVA PHARMACEUTICALS HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (29,918,802)	$ (39,260,837)
Adjustments to reconcile net loss to net cash used in operating activities		
Change in fair value of warrant liabilities	(717,645)	239,216
Stock-based compensation expense	1,630,341	3,413,354
Changes in operating assets and liabilities:		
Prepaid clinical trial costs (current and non-current)	(1,282,027)	186,288
Prepaid expenses and other current assets	(411,798)	(115,401)
Accounts payable	2,291,186	328,837
Accrued expenses and other current liabilities	(5,135,171)	6,884,190
Net cash used in operating activities	(33,543,916)	(28,324,353)
Cash flows from financing activities		
Proceeds from issuance of short-term debt	976,904	667,500
Repayment of short-term debt	(518,750)	(667,500)
Proceeds from issuance of common stock, common stock warrants, prefunded warrants and from modification of existing warrants, in offerings, net of issuance costs	23,194,488	27,494,103
Proceeds from exercise of warrants	149	5,677,850
Net cash provided by financing activities	23,652,791	33,171,953
Net (decrease) increase in cash and cash equivalents	(9,891,125)	4,847,600
Cash and cash equivalents, beginning of period	23,367,456	18,519,856
Cash and cash equivalents, end of period	$ 13,476,331	$ 23,367,456
Supplemental disclosures of cash flow information:		
Cash paid for taxes	$ 3,417	$ 19,754
Cash paid for interest	$ 18,497	$ 30,622
Noncash Investing and Financing Activities:		
Settlement of bonuses in form of stock options	$ 330,816	$ —
Warrant modification recorded in stockholders' equity	$ 1,073,416	$ —
Issuance of common stock warrants	$ 10,421,225	$ —
Issuance of prefunded warrants	$ 470,057	$ —
Issuance of underwriter warrants	$ 165,952	$ —
Transaction costs related to offering included in accounts payable	$ 143,136	$ —

The accompanying notes are an integral part of these consolidated financial statements.

1. ORGANIZATION AND NATURE OF OPERATIONS

On December 14, 2020, Reviva Pharmaceuticals Holdings, Inc. (the "Company"), a Delaware corporation and the successor by re-domiciliation to Tenzing Acquisition Corp. ("Tenzing"), a British Virgin Islands exempted company, Tenzing Merger Subsidiary Inc., a Delaware corporation and wholly-owned subsidiary of Tenzing ("Merger Sub"), and Reviva Pharmaceuticals, Inc., a Delaware corporation (together with its consolidated subsidiary), consummated a business combination (the "Business Combination") through the merger of Merger Sub with and into Reviva Pharmaceuticals, Inc. (the "Merger"), in accordance with the Agreement and Plan of Merger, dated as of July 20, 2020 (the "Merger Agreement"), by and among Tenzing, Merger Sub, Reviva Pharmaceuticals, Inc., and the other parties thereto. Pursuant to the Merger Agreement, at the effective time of the Merger, Merger Sub merged with and into Reviva Pharmaceuticals, Inc., with Reviva Pharmaceuticals, Inc. as the surviving company in the Merger and, after giving effect to such Merger, Reviva Pharmaceuticals, Inc. becoming a wholly-owned subsidiary of Reviva Pharmaceuticals Holdings, Inc. In these notes to the consolidated financial statements, unless otherwise specified or the context indicates otherwise, references to the "Company," "Reviva," "we," "us" and "our" refer to Reviva Pharmaceuticals Holdings, Inc. and its consolidated subsidiaries.

Reviva Pharmaceuticals, Inc. was originally incorporated in the state of Delaware and commenced operations on May 1, 2006 and its Indian subsidiary, Reviva Pharmaceuticals India Pvt. Ltd. was incorporated in 2014. The Company is a late-stage pharmaceutical company developing new therapies that seek to address unmet medical needs in the areas of central nervous system ("CNS"), inflammatory and cardiometabolic diseases.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND BASIS OF PRESENTATION

Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The summary of significant accounting policies presented below is designed to assist in understanding the Company's consolidated financial statements. Such consolidated financial statements and accompanying notes are the representations of Company's management, who is responsible for their integrity and objectivity.

Reclassifications

Certain amounts in the prior year's consolidated financial statements, as of and for the year ended December 31, 2023 have been reclassified to conform to the current period's presentation. This involved disclosing separately, prepaid clinical trial costs from the prepaid expenses and other current assets balance, which were previously disclosed in the aggregate. This also involved disclosing separately interest expense, interest income, and other income, net, which were previously disclosed in the aggregate. These reclassifications had no effect on the Company's loss from operations, net loss, or net loss per share

Principles of consolidation

The accompanying consolidated financial statements include the accounts of Reviva Pharmaceuticals Holdings, Inc. and its wholly owned subsidiaries Reviva Pharmaceuticals, Inc and Reviva Pharmaceuticals, India Pvt Ltd. The Company's foreign subsidiary's functional currency is the U.S. dollar. The Company recognizes a foreign currency gain or loss each reporting period, on translation of its foreign subsidiary's financial information on consolidation. Any such foreign currency gain or loss is recognized as part of other expense, net, on the consolidated statement of operations. The accompanying consolidated financial statements have been prepared in accordance with U.S. GAAP. All transactions and balances between the parent and its subsidiaries have been eliminated in consolidation.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation and used by chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company's Chief operating decision-maker ("CODM"), the Company's chief executive officer, view the Company's operations and manages its business as a single operating segment. See Note 9 for more information.

Liquidity and going concern

The Company has incurred losses since inception and as of December 31, 2024 the Company had a working capital surplus of approximately $0.1 million, an accumulated deficit of $164.3 million and cash and cash equivalents on hand of approximately $13.5 million. The Company's net loss for the years ended December 31, 2024 and 2023, was approximately $29.9 million and $39.3 million, respectively. The Company expects to incur significant expenses and increased operating losses for the next several years. The Company expects its expenses to increase in connection with its ongoing activities to research, develop and commercialize its product candidates. The Company will need to generate significant revenues to achieve profitability, and it may never do so.

The Company's current cash on hand is not sufficient to satisfy its operating cash needs for the 12 months from the filing of this Annual Report on Form 10-K. The Company believes that it has adequate cash on hand to cover anticipated outlays into the second quarter of 2025, but will need additional fundraising activities and cash on hand during the second quarter of fiscal year 2025. The Company has based this estimate, however, on assumptions that may prove to be wrong, and could spend available financial resources much faster than it currently expects. The Company will need to raise additional funds to continue funding its development efforts and operations. The Company intends to secure such additional funding, although there are no guarantees or commitments for additional funding. These conditions raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date the financial statements are issued. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. The Company will seek to fund its operations through public or private equity or debt financings or other sources, which may include collaborations with third parties. During 2024, the Company raised capital through registered financial offerings (Note 4). Adequate additional financing may not be available to the Company on acceptable terms, or at all. Should the Company be unable to raise sufficient additional capital, the Company may be required to undertake cost-cutting measures including delaying or discontinuing certain clinical activities. These circumstances raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods covered by the consolidated financial statements and accompanying notes. Significant items subject to such estimates and assumptions include clinical trial costs, fair value of stock-based compensation, and fair value of warrants. Actual results could differ materially from such estimates under different assumptions or circumstances.

Concentration of credit risk and other risks and uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. Substantially, all the Company's cash and cash equivalents are held in demand deposit and money market funds at three financial institutions. Deposits in financial institutions may, from time to time, exceed federally insured limits. Amounts held in demand deposit in excess of federally insured limits, totaled $937,004 and $786,971 as of December 31, 2024 and 2023, respectively. The Company has not experienced any losses on its deposits of cash.

The Company is subject to all of the risks inherent in a clinical-stage company developing new pharmaceutical products. These risks include, but are not limited to, limited management resources, dependence upon medical acceptance of the product in development, regulatory approvals, successful clinical trials, availability and willingness of patients to participate in human trials, and competition in the pharmaceutical industry.

The Company contracts with vendors and consultants to provide services related to the Company's research and development. Costs and expenses incurred that represented 10% or more of research and development costs for the years ended December 31, 2024 and 2023 are described as follows. During the year ended December 31, 2024, costs from two vendors represented 40% of and 14% of total research and development expenses. During the year ended December 31, 2023, costs from one vendor represented 62% of total research and development expenses.

The Company's operating results may be materially affected by the foregoing factors.

Cash and cash equivalents

As of December 31, 2024, and 2023, the Company's cash was maintained in demand deposit forms at three financial institutions. The Company considers any highly liquid investments, such as money market funds, with an original maturity of three months or less to be cash and cash equivalents.

The components of cash and cash equivalents were as follows:

	Year Ended December 31,	
	2024	**2023**
Cash on deposit	$ 1,272,704	$ 1,155,636
Money market funds (cash equivalents)	12,203,627	22,211,820
Cash and cash equivalents	$ 13,476,331	$ 23,367,456

Leases

The Company determines if an arrangement is a lease at inception and classifies its leases at commencement. Operating leases are presented as right-of-use ("ROU") assets and the corresponding lease liabilities are included in lease liability, current and lease liability, on the Company's balance sheets. ROU assets represent the Company's right to use an underlying asset, and lease liabilities represent the Company's obligation to make lease payments in exchange for the ability to use the asset for the duration of the lease term. The option to extend a lease is included in the lease term only when it is reasonably certain that the Company will elect that option. Additionally, the Company does not record ROU assets or lease liabilities for short-term leases that have a term of twelve months or less at lease commencement.

ROU assets and lease liabilities are recognized at the commencement date and determined using the present value of the future minimum lease payments over the lease term. For any identified leases not determined to be short-term, The Company uses an incremental borrowing rate based on an estimated rate of interest for collateralized borrowing for any leases that do not include an implicit interest rate. Where applicable, The estimated incremental borrowing rate considers market data, actual lease economic environment, and the lease term at commencement date.

Fair Value Measurements

Accounting Standards Codification ("ASC") 820, *Fair Value Measurements* ("ASC 820"), defines fair value, establishes a framework for measuring fair value in U.S. GAAP and expands disclosures about fair value measurements. ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The three levels of the fair value hierarchy under ASC 820 are described below:

- Level 1 - Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

- Level 2 - Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.

- Level 3 - Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

In determining the fair value of equity classified warrants, the Company utilizes the Black-Scholes-Merton model using assumptions regarding volatility of the Company's common share price, expected term of the warrants, expected divided rate, and risk-free interest rates. In determining the fair value of liability classified warrants, the Company utilizes a Lattice model using assumptions regarding volatility of the Company's common share price, expected term of the warrants, expected dividend, and risk-free interest rates. These assumptions are described as:

- Expected term: The Company's expected term represents the period between the valuation date and the expiration date of the warrant, however if an estimated liquidation event is expected to occur and the warrants are effected by said liquidation event, the period between the valuation date and that event would be used instead.

- Expected volatility: Expected volatility for equity classified awards is based on historical stock volatility data for a peer set of similar public companies with sufficient trading history, over the expected term of the warrant. Expected volatility for liability classified warrants is based on the volatility implied by the public warrant market price when sufficient data is available, otherwise it is based on a peer set of similar public companies.

- Expected dividend: The Black-Scholes-Merton valuation model calls for a single expected dividend yield as an input. The Company has never paid dividends and has no plans to pay dividends.

- Risk-free interest rate: The risk-free interest rate used in the Black-Scholes-Merton valuation method is based on the U.S. Treasury zero-coupon issues in effect at the valuation date for periods corresponding with the expected term of the warrant.

Due to their short maturities, the carrying amounts for cash and cash equivalents, prepaid clinical trial costs, prepaid expenses and other current assets, accounts payable, accrued clinical expenses, accrued compensation, short-term debt, and other accrued liabilities approximate their fair value.

Clinical trial costs

We record clinical trial costs as they are incurred. For any unbilled costs as of each reporting date, we determine the amounts to accrue by obtaining reports from the Company's contract research organization ("CRO") and communicating with our personnel and suppliers to identify services that have been performed, but not yet billed. We further validate the completeness of our accruals by reconciling payments and invoices, and reviewing vendor contracts and purchase orders. As necessary, we obtain milestones and percentage completion reports from vendors and will estimate the level of service performed and the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of the actual cost.

Our estimated accrued expenses are based on facts and circumstances known to us at that time. We will confirm the accuracy of our estimates with the service providers and adjust if necessary. The significant estimates in our accrued clinical trial costs include the calculation of patient visits incurred, but not yet reported by the vendor. The calculation involves the use of key inputs and assumptions such as estimated budget, estimated unreported costs based on historical trending of reported costs to date, and projected costs remaining until the conclusion of the trials.

These estimates are primarily based on communications with the third-party service providers, the Company's estimates of accrued clinical trial costs and information available at each balance sheet date. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. The estimates are

trued up to reflect the best information available at the time of the consolidated financial statement issuance. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's estimate of the status and timing of services performed relative to the actual status and timing of services performed may vary.

Research and development costs

Research and development costs are charged to operating expenses as incurred. Research and development costs include, but are not limited to, costs associated with the Company's clinical trials, payroll and personnel expenses, stock-based compensation charges for those individuals involved in ongoing research and development efforts, laboratory supplies and consulting costs. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

The Company estimates preclinical studies and clinical trial expenses based on the services performed pursuant to contracts with research institutions and CROs that conduct and manage preclinical studies and clinical trials on the Company's behalf.

General and administrative costs

General and administrative costs are charged to operating expenses as incurred. General and administrative costs include, but are not limited to, payroll and personnel expenses, travel and entertainment, consulting costs, professional services, conference and meeting costs, legal expenses and overhead, including rent and utilities.

Income taxes

The Company utilizes FASB ASC 740, *Income Taxes*, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the tax basis of assets and liabilities and their financial reporting amounts based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. A valuation allowance is recorded when it is "more likely-than-not" that a deferred tax asset will not be realized.

The Company accounts for income taxes using the liability method whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, to reduce deferred tax assets to their estimated realizable value.

In evaluating the ability to recover its deferred income tax assets, the Company considers all available positive and negative evidence, including its opening results, ongoing tax planning, and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. The Company generated a deferred tax asset through net operating loss ("NOL") carry-forward. However, a valuation allowance of 100% has been established due to the uncertainty of the Company's realization of the net operating loss carry forward prior to its expiration. In the event the Company determines that it would be able to realize its deferred income tax assets in the future in excess of their net recorded amount, it would make an adjustment to the valuation allowance that would reduce the provision for income taxes. Conversely, in the event that all or part of the net deferred tax assets are determined not to be realizable in the future, an adjustment to the valuation allowance would be charged to earnings in the period such determination is made.

Stock-based compensation

Stock-based compensation is calculated based on the requirements of ASC 718, *Share-Based Payments* ("ASC 718"), which requires recognition in the consolidated financial statements of the cost of employee and director services received in exchange for an award of equity instruments over the period the employee or director is required to perform the services in exchange for the award (presumptively, the vesting period). ASC 718 also requires measurement of the cost of employee and director services received in exchange for an award based on the grant-date fair value of the award. The fair value of the award is recognized as expense based upon the vesting terms of the award over the requisite service period. The Company accounts for forfeited awards as they occur.

In determining the fair value of awards, the Company utilizes the Black-Scholes-Merton model using assumptions regarding volatility of the Company's common share price, expected term, expected divided rate, and risk-free interest rates as described below:

- Expected term: The Company’s expected term represents the period that the Company’s stock-based awards are expected to be outstanding and is determined using the simplified method.

- Expected volatility: Expected volatility is based on historical stock volatility data for a peer set of similar public companies with sufficient trading history, over the expected term of the awards.

- Expected dividend: The Black-Scholes-Merton valuation model calls for a single expected dividend yield as an input. The Company has never paid dividends and has no plans to pay dividends.

- Risk-free interest rate: The risk-free interest rate used in the Black-Scholes-Merton valuation method is based on the U.S. Treasury zero-coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

Short-term debt

In January 2024, the Company obtained financing for certain Director and Officer liability insurance policy premiums. The governing agreement assigns the lender a first priority lien on and security interest in the financed policies and any additional premium required in the financed policies.

The total premiums, taxes, and fees financed was $518,750, of which a principal balance of $415,000 was financed after accounting for the up-front payment made. The financing arrangement has an annual percentage interest rate of 7.99% and a term of 10 months, with ten payments, inclusive of interest, payable on a monthly basis through November 2024.

In December 2024, the Company obtained new financing for the renewal of these policies. The total premiums, taxes, and fees financed was $458,154. The financing arrangement has an annual percentage interest rate of 7.90% and a term of 10 months, with ten payments, inclusive of interest, payable on a monthly basis beginning January 2025 through October 2025.

New Accounting Pronouncements Adopted

In November 2023, the Financial Accounting Standards Board ("FASB") issued an Accounting Standards Update ("ASU") 2023-07, with the goal of enhancing segment disclosures under Topic 280 – *Segment Reporting*, which requires public entities to disclose significant segment expenses regularly provided to the chief operating decision-maker. Public entities with a single reporting segment have to provide all disclosures required by ASC 280, including the significant segment expense disclosures. This Update is applicable for all public entities. The amendments in this Update are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company adopted the provisions of ASU 2023-07 as of December 31, 2024 on a retrospective basis. The adoption did not have a material impact on the consolidated financial statements, refer to Note 9, *Segment Information*.

New Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Income Taxes* (Topic 740), *Improvements to Income Tax Disclosures*. This Update enhances the transparency and usefulness of income tax disclosures, particularly in the rate reconciliation table and disclosures about income taxes paid. The guidance also eliminates certain existing requirements related to uncertain tax positions and unrecognized deferred tax liabilities. The amendments in this Update are effective for annual periods beginning after December 15, 2024. Early adoption of the amendments is permitted for annual financial statements that have not yet been issued. The Company is in the process of evaluating the impact of this new guidance on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, to require disclosure, in the notes to financial statements, of specified information about certain costs and expenses. The effective date for the standard is for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is in the process of evaluating the impact of this new guidance on its consolidated financial statements.

3. LOSS PER SHARE

Basic and diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of common shares and pre-funded warrants outstanding during the period. Diluted net loss per share includes potentially dilutive securities such as stock, and options, warrants to purchase common stock (excluding warrants that are exercisable for $0.0001 per warrant) unless the result of inclusion would be anti-dilutive. These securities have been excluded from the calculation of diluted net loss per share for the years ended December 31, 2024 and 2023, because all such securities are anti-dilutive for all periods presented.

The components of basic and diluted net loss per share were as follows:

	Year Ended December 31,	
	2024	**2023**
Numerator:		
Net loss	$ (29,918,802)	$ (39,260,837)
Denominator:		
Weighted-average common shares outstanding – basic and diluted	33,147,424	23,798,203
Net loss per share – basic and diluted	$ (0.90)	$ (1.65)

The following table summarizes the Company's potentially dilutive securities, in common share equivalents, which have been excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive:

	Year Ended December 31,	
	2024	2023
Shares issuable upon exercise of stock options	2,559,440	1,580,574
Shares issuable upon exercise of warrants to purchase common stock (excluding 1,968,765 warrants that are exercisable for $0.0001 per warrant as of December 2024 and 2023)	45,782,603	20,883,869
	48,342,043	22,464,443

The diluted net loss per share computation equals basic net loss per share for the years ended December 31, 2024 and 2023 because the Company had a net loss and the impact of the assumed exercise of stock options and certain warrants would be anti-dilutive.

4. WARRANTS

The following is a summary of the Company's warrant activity (number of common stock shares underlying the warrants) for the years ended December 31, 2024 and 2023:

Warrant Issuance	Issuance	Exercise Price	Outstanding, December 31, 2022	Warrant Shares Granted	Warrant Shares Exercised	Warrant Shares Cancelled/ Expired	Outstanding, December 31, 2023	Expiration
SPAC Public Warrants	December 2020	$ 11.50	6,881,313	—	—	—	6,881,313	December 2025
June 2021 Common Stock Warrants*	June 2021	$ 4.125	6,871,651	—	(226,610)	—	6,645,041	May 2026
Pre-Public Private Company Warrants	December 2020	$ 22.99	120,456	—	—	—	120,456	July 2025
September 2022 Private Pre-Funded Warrants	September 2022	$ 0.0001	1,383,399	—	—	—	1,383,399	September 2027
September 2022 Common Stock Warrants	September 2022	$ 2.40	3,359,684	—	(1,976,285)	—	1,383,399	September 2027
November 2023 Common Stock Warrants**, ***	November 2023	$ 5.00	—	5,853,660	—	—	5,853,660	November, 2028
November 2023 Pre-Funded Warrants	November 2023	$ 0.0001	—	585,366	—	—	585,366	November, 2028
			18,616,503	6,439,026	(2,202,895)	—	22,852,634	

* In August 2024, 2,199,975 of these warrant shares were modified to reduce the exercise price from $4.125 per warrant share, to $0.7964 per warrant share and to extend the expiration of these warrants from May 2026 to August 2029. The breakout of these warrant shares has been reflected in the 2024 warrant rollforward table, below.
** In May 2024, 1,365,854 of these warrants were modified to reduce the exercise price from $5.00 per warrant share, to $1.455 per warrant share and to extend the expiration of these warrants from November 2028 to May 2029. The breakout of these warrant shares has been reflected in the 2024 warrant rollforward table, below.
*** In August 2024, 2,536,586 of these warrants (separate from the May 2024 modification) were modified to reduce the exercise price from $5.00 per warrant share, to $0.7964 per warrant share and to extend the expiration of these warrants from November 2028 to August 2029. The breakout of these warrant shares has been reflected in the 2024 warrant rollforward table, below.

Warrant Issuance	Issuance	Exercise Price	Outstanding, December 31, 2023	Warrant Shares Granted	Warrant Shares Exercised	Warrant Shares Cancelled/ Expired	Outstanding, December 31, 2024	Expiration
SPAC Public Warrants	December 2020	$ 11.50	6,881,313	—	—	—	6,881,313	December 2025
June 2021 Common Stock Warrants	June 2021	$ 4.125	4,445,066	—	—	—	4,445,066	May 2026
June 2021 Common Stock Warrants (August 2024 Amended)	June 2021	$ 0.7964	2,199,975	—	—	—	2,199,975	August 2029
Pre-Public Private Company Warrants	December 2020	$ 22.99	120,456	—	—	—	120,456	July 2025
September 2022 Private Pre-Funded Warrants	September 2022	$ 0.0001	1,383,399	—	—	—	1,383,399	September 2027
September 2022 Common Stock Warrants	September 2022	$ 2.40	1,383,399	—	—	—	1,383,399	September 2027
November 2023 Common Stock Warrants	November 2023	$ 5.00	1,951,220	—	—	—	1,951,220	November, 2028
November 2023 Common Stock Warrants (May 2024 Amended)	November 2023	$ 1.455	1,365,854	—	—	—	1,365,854	May 2029
November 2023 Common Stock Warrants (August 2024 Amended)	November 2023	$ 0.7964	2,536,586	—	—	—	2,536,586	August 2029
November 2023 Pre-Funded Warrants	November 2023	$ 0.0001	585,366	—	—	—	585,366	November, 2028
May 2024 Common Stock Warrants	May 2024	$ 1.455	—	1,898,734	—	—	1,898,734	May 2029
August 2024 Common Stock Warrants	August 2024	$ 0.7964	—	4,761,905	—	—	4,761,905	August 2029
August 2024 Pre-Funded Warrants	August 2024	$ 0.0001	—	1,485,643	(1,485,643)	—	—	August 2029
August 2024 Underwriter Warrants	August 2024	$ 1.3125	—	238,095	—	—	238,095	August 2029
December 2024 Series A Common Stock Warrants	December 2024	$ 1.50	—	6,000,000	—	—	6,000,000	June 2025
December 2024 Series B Common Stock Warrants	December 2024	$ 1.50	—	12,000,000	—	—	12,000,000	December 2029
			22,852,634	26,384,377	(1,485,643)	—	47,751,368	

November 2023 Registered Direct Offering

On November 20, 2023, the Company completed a registered direct offering (the "November 2023 Offering"), priced at the market under Nasdaq rules, with several healthcare-focused institutional investors, and an investment vehicle managed by a firm affiliated with a member of the Company's Board of Directors (the "Director Affiliate" and collectively, the "Purchasers"), and the Company sold and issued to the Purchasers an aggregate of (i) 5,268,294 shares (the "Shares") of the Company's common stock, par value $0.0001 per share (the "Common Stock"), (ii) pre-funded warrants (the "November 2023 Pre-Funded Warrants") exercisable for an aggregate of up to 585,366 shares of Common Stock, and (iii) warrants (the "November 2023 Common Stock Warrants") exercisable for an aggregate of up to 5,853,660 shares of Common Stock. The public offering price for each share of Common Stock and accompanying warrant to purchase one share of Common Stock was $5.125 and the public offering price for each November 2023 Pre-Funded Warrant and accompanying November 2023 Warrant to purchase one share of Common Stock was $5.1249. The net proceeds to the Company from the November 2023 Offering were approximately $27.5 million, after deducting placement offering costs, agent fees and expenses and other offering expenses payable by the Company.

The fair value of the November 2023 Common Stock Warrants and November 2023 Pre-Funded Warrants was determined utilizing a Black-Scholes-Merton model considering all relevant assumptions current at the date of issuance. The grant date relative fair value of the November 2023 Common Stock Warrants and the November 2023 Pre-Funded Warrants was estimated to be $23.8 million on November 15, 2023 and such warrants are classified as equity. Refer to Note 2, *Summary of Significant Accounting Policies and Basis of Presentation*, for further detail regarding how assumptions were determined.

The following assumptions and key inputs were used to value the November 2023 Common Stock Warrants and November 2023 Pre-Funded Warrants at the date of issuance:

	November 2023 Warrants	November 2023 Pre-Funded Warrants
Risk-free interest rate	4.5%	4.5%
Expected term (years)	5.0	5.0
Expected volatility	89.0%	89.0%
Stock price on valuation date	$ 5.00	$ 5.00
Exercise price	$ 5.12	$ 0.0001
Expected dividend	—%	—%

The Company evaluated the November 2023 Warrants and the November 2023 Pre-Funded Warrants in accordance with the guidance at ASC 480, Distinguishing Liabilities from Equity and ASC 815-40, Derivatives and Hedging, and determined that they should be classified as equity instruments, with no recurring fair value measurement required. The warrants are indexed to the Company's common stock and are required to be settled through physical settlement or net share settlement, if exercised. Accordingly, the warrants were recorded at their grant date fair value with no subsequent remeasurement.

May 2024 Registered Direct Offering

On May 29, 2024, the Company completed a registered direct offering (the "May 2024 Offering"), priced at the market under Nasdaq rules, and the Company sold and issued an aggregate of (i) 1,898,734 shares of its common stock, and (ii) warrants (the "May 2024 Common Stock Warrants") exercisable for an aggregate of up to 1,898,734 shares of its common stock. The public offering price for each share of common stock and accompanying May 2024 Warrant to purchase one share of common stock was $1.58. The May 2024 Common Stock Warrants have a term of 5 years and expire on May 29, 2029. The net proceeds to the Company from the May 2024 Offering were $2.8 million, after deducting placement offering costs, agent fees and expenses and other offering expenses payable by the Company, of $0.4 million.

The Company evaluated the May 2024 Common Stock Warrants in accordance with the guidance at ASC 480, Distinguishing Liabilities from Equity and ASC 815-40, Derivatives and Hedging, and determined that they should be classified as equity instruments, with no recurring fair value measurement required. The May 2024 Common Stock Warrants are indexed to the Company's common stock and are required to be settled through physical settlement, subject to certain conditions, or net share settlement, if exercised. Accordingly, the May 2024 Common Stock Warrants were recorded at their grant date fair value with no subsequent remeasurement.

The fair value of the May 2024 Common Stock Warrants was determined utilizing a Black-Scholes-Merton model, considering all relevant assumptions current at the date of issuance. Refer to Note 2, *Summary of Significant Accounting*

Policies and Basis of Presentation, for further detail regarding how assumptions were determined. The grant date relative fair value of the May 2024 Common Stock Warrants was estimated to be approximately $1.1 million recognized to additional paid-in capital in the consolidated balance sheet as the May 2024 Common Stock Warrants were determined to be equity classified, with the corresponding debit as an issuance cost of the related equity offering.

The following assumptions and key inputs were used to value the May 2024 Common Stock Warrants at the date of issuance:

Risk-free interest rate		4.6%
Expected term (years)		5
Expected volatility		93.00%
Stock price on valuation date	$	1.34
Exercise price	$	1.46
Expected dividend		—%

Accounting for Warrant Modification

In connection with the May 2024 Offering, on May 28, 2024, the Company entered into a warrant amendment agreement with the purchaser party to the Purchase Agreement, pursuant to which the Company agreed to amend the purchaser's existing warrants to purchase 1,365,854 shares of common stock at an exercise price of $5.00 per share issued in November 2023 (the "May 2024 Existing Warrants") in consideration for such purchaser party's participation and purchase of approximately $3.0 million of securities in the May 2024 Offering and the payment of $0.2 million to (i) lower the exercise price of the May 2024 Existing Warrants to $1.455 per share and (ii) amend the expiration date of the May 2024 Existing Warrants to five years following the closing of the May 2024 Offering, effective upon the closing of the May 2024 Offering on May 29, 2024.

ASC Topic 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC Topic 815, Derivatives and Hedging ("ASC 815") require issuers to account for modifications or exchanges of freestanding equity-classified written call options (e.g., warrants) that remain equity classified after the modification or exchange based on the economic substance of the modification or exchange. Pursuant to ASC 480 and ASC 815, the Company accounts for modifications of equity-classified warrant agreements by recording any increase in fair value of the modified equity-classified warrant as an equity issuance cost that reduces additional paid-in capital. The increase in the fair value of the modified May 2024 Existing Warrants was determined to be $0.2 million.

The following assumptions and key inputs were used to value the modification of the May 2024 Existing Warrants immediately before the modification and immediately after the modification:

		Immediately before the modification		**Immediately after the modification**
Risk-free interest rate		4.70%		4.60%
Expected term (years)		4.5		5.0
Expected volatility		97.00%		93.00%
Stock price on valuation date	$	1.34	$	1.34
Exercise price	$	5.00	$	1.46
Expected dividend		—%		—%

August 2024 Underwritten Offering

On August 22, 2024, the Company completed an underwritten offering and the Company sold and issued (i) 3,276,262 shares of common stock, (ii) pre-funded warrants (the "August 2024 Pre-Funded Warrants") exercisable for an aggregate of up to 1,485,643 shares of common stock, and (iii) warrants (the "August 2024 Common Stock Warrants") exercisable for an aggregate of 4,761,905 shares of common stock (the "August 2024 Offering"). The public offering price for each share of common stock and accompanying August 2024 Common Stock Warrants to purchase one share of common stock (including the pricing for the warrant repricing described below) was $1.05, and the public offering price for each August 2024 Pre-Funded Warrant and accompanying August 2024 Warrant to purchase one share of common stock was $1.0499. The net proceeds to the Company from the August 2024 Offering were approximately $3.6 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company of approximately $1.4 million.

Upon the closing of the August 2024 Offering, the Company issued to the Underwriter warrants to purchase up to 238,095 shares of common stock (the "August 2024 Underwriter Warrants"). The August 2024 Underwriter Warrants are exercisable at an exercise price of $1.3125 per share and are exercisable during the five-year period commencing six months after the closing date of the August 2024 Offering.

The Company evaluated the August 2024 Common Stock Warrants and August 2024 Pre-funded Warrants in accordance with the guidance at ASC 480, *Distinguishing Liabilities from Equity* and ASC 815-40, *Derivatives and Hedging*, and determined that they should be classified as equity instruments, with no recurring fair value measurement required. The August 2024 Common Stock Warrants are indexed to the common stock and are required to be settled through physical settlement, subject to certain conditions, or net share settlement, if exercised. Accordingly, the August 2024 Common Stock Warrants were recorded at their grant date fair value with no subsequent remeasurement.

The Company evaluated the August 2024 Underwriter Warrants in accordance with the guidance at ASC 718, Compensation-Stock Compensation, and determined that they should be classified as equity instruments, with no recurring fair value measurement required. The August 2024 Underwriter Warrants are indexed to the common stock and are required to be settled through physical settlement, subject to certain conditions, or net share settlement, if exercised. Accordingly, the August 2024 Underwriter Warrants were recorded at their grant date fair value with no subsequent remeasurement. Further, the Company recognized the August 2024 Underwriter Warrants as a stock issuance costs as they are issued for services in connection with an offering, and therefore will account for these as a reduction of the proceeds in the August 2024 Offering.

The fair value of the August 2024 Common Stock Warrants, August 2024 Pre-funded Warrants, and August 2024 Underwriter Warrants were determined utilizing a Black-Scholes-Merton model, considering all relevant assumptions current at the date of issuance. Refer to Note 2, *Summary of Significant Accounting Policies and Basis of Presentation*, for further detail regarding how assumptions were determined. The grant date relative fair value of the August 2024 Common Stock Warrants, August 2024 Pre-funded Warrants and August 2024 Underwriter Warrants was estimated to be approximately $1.2 million, $0.5 million, and $0.2 million, respectively, and were recognized as additional paid-in capital in the consolidated balance sheet as the August 2024 Common Stock Warrants, August 2024 Pre-funded Warrants, and August 2024 Underwriter Warrants were determined to be equity classified, with the corresponding debit as an issuance cost of the related equity offering.

The following assumptions and key inputs were used to value the August 2024 Common Stock Warrants, August 2024 Pre-funded Warrants, and August 2024 Underwriter Warrants at the date of issuance:

	August 2024 Common Stock Warrants	August 2024 Pre-Funded Warrants	August 2024 Underwriter Warrants
Risk-free interest rate	3.7%	3.7%	3.7%
Expected term (years)	5	5	5
Expected volatility	111.00%	111.00%	111.00%
Stock price on valuation date	$ 0.90	$ 0.90	$ 0.90
Exercise price	$ 0.7964	$ 0.0001	$ 1.3125
Expected dividend	—%	—%	—%

Accounting for Warrant Modification

In connection with the August 2024 Offering, on August 20, 2024, the Company entered into a warrant amendment agreement (the "August 2024 Warrant Amendment Agreement") with the purchaser of the August 2024 Pre-Funded Warrants, pursuant to which the Company agreed to amend the purchaser's (i) warrants to purchase up to 2,536,586 shares of common stock at an exercise price of $5.00 per share issued in November 2023 and (ii) warrants to purchase up to 2,199,975 shares of common stock at an exercise price of $4.125 per share issued in June 2021 (together, the "August 2024 Existing Warrants"), in consideration for such investor's participation in the August 2024 Underwritten Offering and the payment of $0.125 per August 2024 Existing Warrant (which amount is included in the $1.05 offering price above) to (i) lower the exercise price of the August 2024 Existing Warrants to $0.7964 per share and (ii) amend the expiration date of the August 2024 Existing Warrants to five years following the closing of the August 2024 Offering, effective upon the closing of the August 2024 Offering on August 22, 2024.

ASC Topic 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC Topic 815, Derivatives and Hedging ("ASC 815") require issuers to account for modifications or exchanges of freestanding equity-classified written call options (e.g., warrants) that remain equity classified after the modification or exchange based on the economic substance of the modification or exchange. Pursuant to ASC 480 and ASC 815, the Company accounts for modifications of equity-classified warrant agreements by recording any increase in fair value of the modified equity-classified warrant as an equity issuance cost that reduces additional paid-in capital. The increase in the fair value of the modified August 2024 Existing Warrants was determined to be $0.8 million.

The following assumptions and key inputs were used to value the modification of the warrants immediately before and immediately after the modification. Refer to Note 2, *Summary of Significant Accounting Policies and Basis of Presentation*, for details related to the determination of fair value for warrants:

	Immediately before the modification		Immediately after the modification	
	June 2021 Common Stock Warrants	November 2023 Common Stock Warrants	June 2021 Common Stock Warrants	November 2023 Common Stock Warrants
Risk-free interest rate	4.10%	3.70%	3.70%	3.70%
Expected term (years)	1.76	4.25	5.00	5.00
Expected volatility	100.00%	111.00%	111.00%	111.00%
Stock price on valuation date	$ 1.14	$ 1.14	$ 1.14	$ 1.14
Exercise price	$ 4.1250	$ 5.0000	$ 0.7964	$ 0.7964
Expected dividend	—%	—%	—%	—%

December 2024 Underwritten Offering

On December 18, 2024, the Company completed an underwritten offering and the Company sold and issued (i) an aggregate of 12,000,000 shares of the Company's common stock, par value $0.0001 per share ("Common Stock"), (ii) Series A warrants exercisable for an aggregate of up to 6,000,000 shares of Common Stock (the "Series A Common Stock Warrants") and (iii) Series B warrants exercisable for an aggregate of up to 12,000,000 shares of Common Stock (the "Series B Common Stock Warrants" and together with the Series A Common Stock Warrants, the "December 2024 Common Stock Warrants"), for aggregate net proceeds of $16.5 million (the "December 2024 Underwritten Offering") after deducting placement offering costs, agent fees and expenses and other offering expenses payable by the Company of $1.5 million.

Each share of Common Stock was sold together with (i) a Series A Common Stock Warrant to purchase 0.5 of a share of Common Stock and (ii) a Series B Common Stock Warrant to purchase one share of Common Stock, at a combined public offering price of $1.50 per share of Common Stock and accompanying December 2024 Common Stock Warrants. The Series A Common Stock Warrants are exercisable immediately, expire six months from the date of issuance on June 18, 2025, and have an exercise price of $1.50 per whole share. The Series B Common Stock Warrants are exercisable immediately, expire 5 years from the date of issuance on December 18, 2029, and have an exercise price of $1.50 per share. The net proceeds to the Company from the December 2024 Underwritten Offering were approximately $16.5 million, after deducting placement offering costs, agent fees and expenses and other offering expenses payable by the Company.

The Company evaluated the December 2024 Common Stock Warrants in accordance with the guidance at ASC 480, Distinguishing Liabilities from Equity and ASC 815-40, Derivatives and Hedging, and determined that they should be classified as equity instruments, with no recurring fair value measurement required. The warrants are indexed to the Company's common stock and are required to be settled through physical settlement or net share settlement, if exercised. Accordingly, the warrants were recorded at their grant date fair value with no subsequent remeasurement.

The fair value of the December 2024 Common Stock Warrants was determined utilizing a Black-Scholes-Merton model considering all relevant assumptions current at the date of issuance. Refer to Note 2, *Summary of Significant Accounting Policies and Basis of Presentation*, for further detail regarding how assumptions were determined. The grant date relative fair value of the Series A and Series B Common Stock Warrants was estimated to be $1.3 million and $6.8 million, respectively and such warrants were recognized as additional paid-in capital in the consolidated balance sheet as they were determined to be equity classified.

The following assumptions and key inputs were used to value the December 2024 Common Warrants at the date of issuance:

	Series A Common Stock Warrants	Series B Common Stock Warrants
Risk-free interest rate	4.3%	4.4%
Expected term (years)	0.50	5.00
Expected volatility	120.00%	111.00%
Stock price on valuation date	$ 1.44	$ 1.44
Exercise price	$ 1.50	$ 1.50
Expected dividend	—%	—%

5. STOCKHOLDERS' EQUITY, STOCK OPTION PLANS, AND STOCK-BASED COMPENSATION

Our authorized capital stock consists of:

- 315,000,000 shares of common stock, par value $0.0001 per share; and
- 10,000,000 shares of preferred stock, par value $0.0001 per share.

As of December 31, 2024 there were 46,579,199 shares of our common stock outstanding, and no shares of preferred stock outstanding. As of December 31, 2023, there were 27,918,560 shares of our common stock outstanding, and no shares of preferred stock outstanding.

Common Stock

Voting. The holders of our common stock are entitled to one vote for each share held of record on all matters on which the holders are entitled to vote (or consent pursuant to written consent). Directors are elected by a plurality of the votes present in person or represented by proxy and entitled to vote.

Dividends. The holders of common stock are entitled to receive, ratably, dividends only if, when and as declared by our board of directors out of funds legally available therefor and after provision is made for each class of capital stock having preference over the common stock.

Liquidation Rights. In the event of the Company's liquidation, dissolution or winding-up, the holders of common stock will be entitled to share, ratably, in all assets remaining available for distribution after payment of all liabilities and after provision is made for each class of capital stock having preference over the Common Stock.

Conversion Right. The holders of common stock have no conversion rights.

Preemptive and Similar Rights. The holders of common stock have no preemptive or similar rights.

Redemption/Put Rights. There are no redemption or sinking fund provisions applicable to the Common Stock. All of the outstanding shares of common stock will be fully-paid and nonassessable.

Preferred Stock

Our board of directors has the authority to issue shares of preferred stock from time to time on terms it may determine, to divide shares of preferred stock into one or more series and to fix the designations, preferences, privileges, and restrictions of preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preference, sinking fund terms, and the number of shares constituting any series or the designation of any series to the fullest extent permitted.

On May 29, 2024, the Company closed the sale of 1,898,734 shares of common stock and the May 2024 Warrants, pursuant to the securities purchase agreement entered into between the Company and several purchasers on May 28, 2024. Refer to Note 4, Warrants, for additional details.

On August 22, 2024, we completed an underwritten offering for the issuance and sale of 3,276,262 shares of our common stock, the August 2024 Warrants and the August 2024 Pre-funded Warrants. Refer to Note 4, *Warrants*, for additional details.

On December 18, 2024 the Company close the sale of the December Underwriting Agreement for the offering, issuance and sale of 12,000,000 shares of common stock and December 2024 Common Stock Warrants. Refer to Note 4, *Warrants*, for additional details.

As of December 31, 2024, the Company has shares of common stock reserved for future issuance as follows:

Shares underlying outstanding warrants	47,751,368
Shares reserved for future issuance under the 2020 Equity Incentive Plan	3,060,506
Stock options outstanding	2,559,440
Total common stock reserved for future issuance	53,371,314

2006 and 2020 Equity Incentive Plans

Following the December 31, 2023 balance sheet date, in accordance with the "evergreen" provision in our 2020 Equity Incentive Plan (the "Evergreen Provision"), an additional 2,791,856 shares were automatically made available for issuance on the first day of 2024, which represents 10% of the number of shares of common stock outstanding on December 31, 2023. As a result, as of December 31, 2024, the Share Reserve available for future awards under the 2020 Equity Incentive Plan stood at 3,060,506 shares, after accounting for the above described 2024 Evergreen Increase, options forfeited and options granted during 2024. Following the December 31, 2024 balance sheet date, in accordance with the Evergreen Provision, an

additional 4,657,919 shares were automatically made available for issuance under the plan on the first day of 2025, representing 10% of the number of shares of common stock outstanding on December 31, 2024.

As of December 31, 2024, there were no outstanding awards under the 2006 Equity Incentive Plan and no new grants of awards are permitted under the 2006 Equity Incentive Plan.

Stock-Based Compensation Expense

The Company records stock-based compensation expense based on the fair value of stock options granted to employees, non-employee consultants and non-employee directors. During the years ended December 31, 2024 and 2023, the Company recorded stock-based compensation expense of approximately $1.6 million and $3.4 million, respectively. As of December 31, 2024, the Company had unrecognized stock-based compensation expense of $2.3 million, which is expected to be recognized over a weighted-average period of 1.9 years.

Determining Fair Value

Refer to Note 2, *Summary of Significant Accounting Policies and Basis of Presentation*, for details related to the determination of fair value for option awards.

The fair value of options granted during the years ended December 31, 2024 and 2023 used the following assumptions and key inputs:

Black-Scholes-Merton Inputs

	December 31, 2024	December 31, 2023
Risk-free interest rate range	3.4% - 4.2%	3.4% - 4.6%
Expected term range (in years)	5.0 - 5.6	5.4 - 6.1
Expected volatility range	111% - 118%	86.5% - 89.5%
Expected dividend yield	—%	—%

The weighted average fair value of stock options granted for the years ended December 31, 2024 and 2023, was $1.01 and $4.59, respectively. The options have a contractual term of 10 years.

Activity under the stock plans for the years ended December 31, 2024 and 2023 is as follows:

	Shares Available for Grant	Number of Options Outstanding	Weighted Average Exercise price per share	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Balance, December 31, 2022	2,600,063	244,774	$ 6.32	8.62	$ —
Granted	(1,595,800)	1,595,800	6.30	—	—
Expired	—	(260,000)	5.04	—	—
Balance, December 31, 2023	1,004,263	1,580,574	6.51	9.11	300,969
Granted*	(1,095,613)	1,095,613	1.21	—	—
Expired/Cancelled	360,000	(116,747)	10.27	—	—
Evergreen plan increase	2,791,856	—	—	—	—
Balance, December 31, 2024	3,060,506	2,559,440	$ 4.07	8.88	$ 683,016
Options vested and exercisable at December 31, 2024		1,643,102	$ 4.48	8.70	$ 362,892

* For the year ended December 31, 2024, the Company settled certain accrued bonus amounts through the issuance of a total of 332,813 stock options to certain employees, in lieu of cash bonuses The fair value of those stock options was approximately $330,816 and this amount was recorded directly to additional paid-in capital on the consolidated balance sheet as the stock options were issued to settle an accrued bonus amount for which the associated expense was previously recognized in the consolidated statement of operations This amount is not included within the expenses disclosed below.

For the years ended December 31, 2024 and 2023, the amount of stock-based compensation expense included within research and development and general and administrative expenses was as follows:

	Year Ended December 31,	
	2024	2023
Research and development	$ 950,247	$ 1,449,982
General and administrative	680,094	1,963,372
Total stock-based compensation expense	$ 1,630,341	$ 3,413,354

6. COMMITMENTS AND CONTINGENCIES

Clinical trials

Since 2010, the Company has entered into multiple clinical trial agreements with medical institutions in the United States, Europe and Asia for the purpose of enrolling patients into various clinical trials. The agreements are substantially similar by trial and include a detailed listing of the clinical trial services for which the Company will pay, how much will be paid for each service, a set-up charge (if any), Investigational Review Board fees, contractual term, and other provisions. The clinical trial services provided by each site generally include the screening of prospective patients and, for those patients to be enrolled in the study, administration of the Company's investigation drug according to the trial protocol, any required hospitalization, ancillary medical supplies, and patient follow-up. Further, each agreement requires the Company to indemnify each respective clinical site against any and all liability, loss, or damage it may suffer as a result of third-party claims; the Company maintains product liability insurance in conjunction with this indemnification. The agreements may be terminated upon 30 days' written notice, subject to conditions of paying all liabilities incurred through the date of termination. Additionally, with each screened patient, the Company incurs expense with other entities engaged to provide independent review of patient medical records.

Indemnification

From time to time, in its normal course of business, the Company may indemnify other parties, with whom it enters into contractual relationships, including lessors and parties to other transactions with the Company. The Company may agree to hold other parties harmless against specific losses, such as those that could arise from a breach of representation, covenant or third-party infringement claims. It may not be possible to determine the maximum potential amount of liability under such indemnification obligations due to the unique facts and circumstances that are likely to be involved in each particular claim and indemnification provision. Historically, there have been no such indemnification claims. The Company has also indemnified its directors and executive officers, to the extent legally permissible, against all liabilities reasonably incurred in connection with any action in which such individual may be involved by reason of such individual being or having been a director or executive officer.

Operating Leases

During the period covered by these consolidated financial statements, the Company had two leases. The first was a twelve-month lease on its former corporate office located at 19925 Stevens Creek Blvd., Suite 100, Cupertino, CA 95014. The monthly lease payment was approximately $1,447 and the lease was renewed in February 2022 and again on February 1, 2023, for another 12-month term. This lease terminated on January 31, 2024. The second lease was for a new corporate office located at 10080 N. Wolfe Road, Suite SW3-200, Cupertino, CA 95014. The monthly lease payment was approximately $4,300 and the lease was entered into beginning December 1, 2023 for a 12-month term and was renewed in January 2025 for an additional twelve months. The operating lease cost on these leases for the years ended December 31, 2024 and 2023 was approximately $50,180 and $20,000, respectively.

Litigation

The Company is not currently a party to any material legal proceedings and is not aware of any pending or threatened claims. From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities.

7. FAIR VALUE MEASUREMENTS

The following tables provide a summary of the assets and liabilities that are required to be measured at fair value on a recurring basis and where they are classified within the fair value hierarchy as of December 31, 2024 and 2023:

	December 31, 2024			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds (cash equivalents)	$12,203,627	$ —	$ —	$12,203,627
Total assets measured and recorded at fair value	$12,203,627	$ —	$ —	$12,203,627
Liabilities:				
Warrant liabilities	$ —	$ —	$ 89,010	$ 89,010
Total liabilities measured and recorded at fair value	$ —	$ —	$ 89,010	$ 89,010

	December 31, 2023			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds (cash equivalents)	$22,211,820	$ —	$ —	$22,211,820
Total assets measured and recorded at fair value	$22,211,820	$ —	$ —	$22,211,820
Liabilities:				
Warrant liabilities	$ —	$ —	$ 806,655	$ 806,655
Total liabilities measured and recorded at fair value	$ —	$ —	$ 806,655	$ 806,655

The following table summarizes the changes in the fair value of the warrant liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3):

	Year Ended December 31,	
	2024	**2023**
Balance, beginning of period	$ 806,655	$ 567,439
Change in fair value of warrant liabilities	(717,645)	239,216
Balance, end of period	$ 89,010	$ 806,655

In prior years, the Company issued warrants to purchase 556,313 shares of common stock in a private-placement (the "Private Warrants") and classified the warrants as derivative liabilities, pursuant to ASC 815, as the Private Warrants have an exercise price that is subject to potential adjustment, with subsequent changes in their fair values to be recognized in the consolidated statement of operations at each reporting date. The Company calculated the fair value of the Private Warrants as of December 31, 2024 and 2023 as $89,010 and $806,655, respectively, using a Lattice model. The assumptions and key inputs used in the Lattice calculation were the following:

	December 31, 2024	December 31, 2023
Risk-free interest rate	4.17%	4.25%
Remaining expected term of Warrants	0.95	1.96
Expected volatility[(1)]	128.70%	89.00%
Stock price on valuation date	$ 1.81	$ 5.15
Exercise price	$ 11.50	$ 11.50
Expected dividend	—%	—%

[(1)] Based on volatility implied by the Company's publicly traded warrant market price.

8. INCOME TAXES

As a result of the Company's history of net operating losses and the full valuation allowance against its deferred tax assets, there was no current or deferred income tax provision other than current state minimum taxes and current foreign taxes for the years ended December 31, 2024 and 2023.

Domestic and international pre-tax income/(loss) consists of the following:

	December 31,	
	2024	2023
United States	$ (29,847,961)	$ (39,301,700)
International	(51,327)	57,812
Loss before income taxes	$ (29,899,288)	$ (39,243,888)

The provision for income taxes is attributable to operations and is comprised of the following:

	December 31,	
	2024	2023
Current:		
Federal	$ —	$ —
State	2,100	2,400
Foreign	17,414	14,549
Current Total	$ 19,514	$ 16,949
Deferred:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Deferred Total	—	—
Provision for Income Taxes	$ 19,514	$ 16,949

Reconciliations to the statutory federal income tax rate and the Company's effective tax rate consist of the following:

	December 31,	
	2024	2023
Statutory federal income tax rate	$ (6,278,850)	$ (8,219,715)
State income taxes, net of federal tax benefits	127,499	(91,612)
State True Up	2,242,134	—
Warrant Expense	(150,705)	50,235
Stock Based Compensation	56,333	86,635
Foreign Rate Differential	(2,053)	2,312
Other Permanent Differences	41,024	17,498
Valuation allowance	3,994,770	8,204,250
Other	(10,638)	(32,654)
Provision for Income Taxes	$ 19,514	$ 16,949

The components of deferred tax assets included on the balance sheet are:

	December 31,	
	2024	2023
NOL Carryforwards	15,687,479	15,264,557
Accruals and Reserves	(28,852)	231,425
Stock-based Compensation	1,135,026	848,987
Capitalized Section 174	14,681,051	11,017,511
Others	13,686	131,090
	31,488,340	27,493,570
Valuation allowance	(31,488,340)	(27,493,570)
Net deferred tax assets	—	—
Deferred income taxes	$ —	$ —

Management has determined based on all the available information that a 100% valuation reserve is required against its deferred tax assets due to the uncertainty surrounding realization of such assets. Total increase in the valuation allowance is $3,994,770 for the year ending December 31, 2024 and was $10,166,952 for the year ending December 31, 2023.

As of December 31, 2024 and 2023, the Company has U.S. Federal net operating loss carryforwards of approximately $71.8 million and $59.1 million, respectively, and state net operating loss carryforwards of approximately $8.7 million and $40.8 million, respectively. Approximately $35.9 million of the U.S. Federal losses begin to expire in 2029. The balance, all post-2017 federal net operating losses may be carried forward indefinitely. Prior to applying the valuation allowance, the deferred tax assets relate mainly to NOL carryforwards, capitalized research expenditures and stock-based compensation.

As of December 31, 2024, the Company had $1.5 million research and development credit carryforwards to offset federal income taxes and $0.2 million of California research credit carryforwards to offset state income taxes. Both the federal and California credits will begin to expire in 2042 if unutilized.

Under the provisions of the Internal Revenue Code, the NOL's and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, respectively, as well as similar state tax provisions. This could limit the amount of tax attributes that the Company can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed several financings since its inception, which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future. Utilization of the net operating loss and tax credits carryforwards may be limited by “ownership change” rules, as defined in Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. This annual limitation may result in the expiration of the net operating losses and credits before utilization.

The Company has elected to recognize interest and penalties related to uncertain tax positions as components of income tax expense. As of December 31, 2024, the Company has no accrual for payment of interest related to unrecognized tax benefits.

The Company's income tax returns for all years remain open to examination by federal and state taxing authorities. The Company does not expect that its unrecognized tax benefit will change significantly in the next 12 months.

As of December 31, 2024 the Company has approximately $1.7 million unrecognized tax benefits that, if recognized, would change its effective rate. The Company's unrecognized tax benefit relates entirely to the federal and California research credits. The total increase in the unrecognized tax benefits was approximately $0.9 million for the year ending December 31, 2024 and $0.7 million for the year ending December 31, 2023.

January 1, 2022	Prior Year Increase/ (Decrease)	Current Year Increase/ (Decrease)	December 31, 2023
$ 136,931	$ 25,000	$ 640,640	$ 802,571

January 1, 2024	Prior Year Increase/ (Decrease)	Current Year Increase/ (Decrease)	December 31, 2024
802,571	$ 134,291	$ 768,063	$ 1,704,925

9. SEGMENT INFORMATION

The Company views its operations and manages its business as one operating and reportable segment focused on developing new therapies that seek to address unmet medical needs in the areas of central nervous system ("CNS"), inflammatory and cardiometabolic diseases. The CODM, manages and allocates resources to the operations of the Company on a consolidated basis, considering primarily research and development expenditures and net loss. This enables the Chief Executive Officer to assess the Company's overall level of available resources and determine how best to deploy these resources in line with long-term company-wide strategic goals.

Consistent with the Company's management reporting, results of operations are reported on a consolidated basis for purposes of segment reporting. Net loss is used to allocate resources and is reported on the consolidated statements of operations. The measure of segment assets is reported on the consolidated balance sheets as cash and cash equivalents.

The CODM does not review any measure of significant segment expenses or segment loss which differ from the level of reporting as reflected on the consolidated statement of operations.

10. SUBSEQUENT EVENTS

February 2025 Option Award

On February 13, 2025, the Compensation Committee of the Board of Directors of the Company approved the grant of certain nonqualified stock options, under the Company's 2020 Equity Incentive Plan, to certain members of senior management of the Company. A total of total of 894,750 options were approved, with a grant date of February 13, 2025. All options had an exercise price of $1.80, being the closing share price of the Company's common stock on the grant date, a term of ten years, expiring February 12, 2035, with 372,689 of those options vesting immediately and the remainder vesting over periods ranging from twenty-two months to thirty-four months.