Schizophrenia is a complex psychiatric disorder affecting ~1% of the population with equal risk across genders. The current diagnosis of schizophrenia and other psychiatric disorders, such as bipolar depression is subjective, not only because of the complex spectrum of symptoms and their overlap with other mental disorders, but also due to the lack of empirical markers or objective tests specific for the disease. The SchizDx project aims to identify up to 50 candidate biomarkers, specifically up or down regulated in drug naive first onset schizophrenics compared to healthy controls. This will allow the project to develop and ultimately commercialize novel biomarker assay panels to aid clinical diagnosis and treatment of patients.

There are 3 key phases of the project 1) Discovering candidate biomarkers that accurately classifying schizophrenia patients, 2) Developing higher throughput assays to measure this biomarker fingerprint and 3) Validating candidate biomarker performance in correctly identifying patients and control samples. The first phase identified schizophrenia specific candidate biomarkers using state of the art proteomic profiling methodologies on serum samples obtained from drug naive, first onset schizophrenia patients vs. carefully matched controls and has greatly exceeded the original goals of the study. >50 candidate biomarkers have been identified that classify patient's samples with high sensitivity and specificity and provide a starting point for development of clinically useful tests. A key feature of this study is that it focused on drug naive, first onset patients rather than on chronic patients who have been treated for many years. This means that our biomarkers reflect the disease process itself rather than the adaptations of many years of antipsychotic drug treatment. Sample collection activities were undertaken to provide serum samples from patients to enable 1) candidate biomarker discovery; 2) initial validation on a wider sample set and 3) further validation in a prospectively collected clinical cohort reproducing the anticipated testing population for any developed diagnostic test. Sample collection for the discovery and initial validation has gone well and has been supplemented by samples from clinical centres outside this project.

Part two of the project focused on the development of high throughput assays to enable validation of candidate biomarkers in terms of a) differentiation of schizophrenia patients from patients suffering from other psychiatric diseases; and b) identification of disease progression and/or treatment response biomarkers. The selected biomarker assays are being developed and combined into a multiplex assay panel suitable for the analysis of patient samples. Initial validation studies on the biomarker assays already selected and developed are very encouraging. Following this initial validation phase, the biomarkers need to be tested to see how well they identify new patients collected prospectively. So a key component of the project is the ongoing, prospective, 3 year clinical trial collecting serum samples from all in patients first admitted to two large psychiatric hospital centres before they are diagnosed. The performance of the test against clinical experts will be assessed. Recruitment of these patient samples has begun.

The project has made excellent progress and we are confident that we will succeed in achieving the goal of developing clinically useful biomarker tests. Following successful completion of the project, Psynova Neurotech Ltd, RBM Inc. and EDI GmbH will seek to provide the early schizophrenia diagnostic assay panel as a commercially available clinical tool for psychiatrists and GPs by establishing the assays in a centralized screening laboratory. In addition, Psynova intends to offer the biomarker assay panel products developed in this work as tools to aid the discovery and development of novel medicines for the treatment of schizophrenia.