Class Exercise

Background:

XYZ Corporation is a supplier of laboratory automation, lab equipment and chemical supplies to various universities, hospitals, and industrial and clinical labs. It recently entered the diagnostic testing market when it acquired IVDPro, a startup which has a promising new molecular testing technology MTSTPro that can be used for viral detection. MTSTPro relies on a combination of novel molecular testing technique but then uses advanced analytics and data science to analyze the data. Because of the advanced techniques, it can provide accurate results in a very short amount of time based on a limited data set. This differentiates it from other testing techniques which rely on greater volumes of data and therefore need more time to detect the presence of the viral strain. Furthermore, by using machine learning, it can also fine tune its analytical engine to further improve speed and accuracy of detection over time. The testing equipment consists of the diagnostic instrument, the test kits (which contain the samples), and a powerful computer to run the data analysis routines. Each test requires a separate test kit. The instrument can test up to 96 samples at the same time.

With the onset of Covid-19 virus, the researchers at IVDPro were able to produce a combination of tests and analytical routines that could accurately and rapidly diagnose the presence of Covid-19 virus. The test is as fast and more accurate as the antigen test. It is currently less accurate than PCR test but generates faster result. IVDPro believes that by doing more fine-tuning of its machine learning, it can approach the accuracy of the PCR tests without compromising its speed to achieve results. XYZ Corporation (parent company of IVDPro) believes it has a great opportunity to commercialize the test by providing a rapid test to the market. However, it faces some challenges that it must overcome:

- Continuing to fine-tune the analytical engine (comprising machine learning) requires experimentation and copious amount of data to be generated and analyzed. That is necessary if it wants to achieve the level of accuracy of current PCR tests.
- The testing material is more complex and expensive to manufacture than other tests that are available in the market. To provide a test at a comparable price as other tests would require XYZ corporation to reduce their production costs and raw materials costs by 50%. To achieve those targets, it would have to use automation in the production of the test kits and buy raw materials and other components from suppliers in large quantities to get bulk discounts.
- XYZ will only target large labs and hospitals in the US that do testing in large numbers as they would be able to afford its testing platform. Smaller labs and test sites – unless they are government supported – may not be able to afford its tests.
- The analytical engine and machine language relies on significant computing power to generate its results and it either must supply a powerful computer to each customer to run the analysis engine or use a hybrid model where the test instrument communicate with analytical routines are available as a cloud service to run the analysis. The machine learning component can then run in the cloud and then can use the aggregate data set coming in from all different testing centers and develop an even more accurate model.

XYZ Corporation decides to proceed with getting regulatory approval for its test in the United States. It believes that its strength in industrial automation and lab equipment can be used to mass produce and reduce it costs to an acceptable level where it can sell to large labs and hospitals that could afford to buy

its instruments. It will take a two-pronged approach: as it gets regulatory approval, it will build a small group of instruments and test kits and work with a small network of large labs that it has a relationship with to do the testing. In parallel, it will bring its development and manufacturing capabilities to scale up production and within one year start mass-producing the instruments and the test kits. Its time to market is initially expected to be longer than its competitors as they have more experience developing instruments and test kits of this nature. Plus, the complexity of the testing material requires many experiments to be performed which in turn generates vast amounts of data that must be analyzed. XYZ corporation therefore must rely on strong automation and IT systems to have a streamlined process and prevent errors in the system.

XYZ expects to generate its profits and the bulk of its revenue through the sale of the test kits. It expects to donate the first 25 instruments to some of its existing customers to jump start the program and to help combat the pandemic. Based on its projection, XYZ believes that the investment will start to generate positive cash flows within the 3rd year. However, once profitable, XYZ corporation believes it can use the tests for detection of new strains of Corona virus and other viral strains. Therefore, it believes making this investment will continue to pay off in the long run. If successful, it believes it can grab 25% of the automated molecular testing market share by 2027 in North America.

General Market Details:

The global COVID-19 diagnostics market size is estimated at USD 84.4 billion in 2020 and is expected to expand at a compound annual growth rate (CAGR) of 3.1% from 2021 to 2027. North America dominated the market with a share of 33.50% in 2020.

Molecular (PCR) testing is projected to dominate the market in 2020 with a revenue share of over 60.0%. Currently, the PCR technique is the most accurate for the detection of COVID-19, thereby leading to a tremendous increase in the adoption of PCR testing kits.

The centralized testing segment is expected to dominate the market in 2020 with over 60.0% share. Currently, most of the COVID-19 tests are carried out in the laboratory environment, thus centralized or laboratory testing is currently the key testing mode in the market. Incorporation of automated high throughput systems facilitates efficient processing of a high number of samples at a given point of time without hampering the quality and integrity of the result. These factors are making centralized testing a critical element in a viable COVID-19-response strategy to circumvent the spread. As a result, hospitals have centralized their lab operations into one core facility, rather than sending specimens to multiple places.

The laboratories segment (which XYZ is targeting) is estimated to account for the largest revenue share of 39.91% in 2020. The increasing number of laboratories are leveraging high-throughput technologies to process COVID-19 tests rapidly and effectively on a large scale.

IT Organization – Current State

XYZ Corporation has a centralized IT organization. It already supports sales and marketing, manufacturing, and supply chain. It has good support for CRM, ERP, MES and SCM systems. It mostly relies on in-house expertise for those systems. It has an internal data center and thus far has made limited use of Cloud capabilities. It relies on Waterfall delivery cycle.

The IT organization has had limited engagement with IVDPro. When IVDPro was bought, it was allowed to maintain a degree of autonomy. As such, XYZ IT only provides a limited set of services to IVDPro including infrastructure, cybersecurity, and core enterprise system support. IVDPro's IT is let by an IT Director that mostly focuses on R&D IT capabilities. The IT Director has a dotted line to the XYZ CIO.

CIO's task

You are the CIO of XYZ corporation. You have been asked to create a strategic plan to support the ramp up of MTSTPro production from a technology standpoint. The strategic plan must keep in mind the following needs:

- You will need to put in place the technology infrastructure, application support, and data management needed to support the laboratory work needed to generate the data needed to enhance the analytical routine. Furthermore, the same labs will be leveraged to improve the tests to identify new variants of the virus accurately and rapidly.
- You will need to also support the ramp up of the manufacturing capability needed to mass produce the instruments, the reagents (chemicals) and support the test kit assembly and development process. This means providing the necessary support the Manufacturing processes that are needed, and any adjustments need to any existing systems.
- Furthermore, you will have to put in place the cloud infrastructure needed to support the analysis platform and build the connectivity needed with the instruments. You will also have to ensure the security of the communication and all patient data to minimize any risk of loss of confidential patient data.
- Any plan that you devise must consider the need for quick ramp up and delivery of the solution to the market but also the future viability of the solution so that IVDPro (and its parent XYZ Corp) can continue to rely on the system thus created for development of future testing capability for other viral strains.