Generx_E4B Innovation Executive Summary

Date: 11/12/2020
Innovation title: Bringing Personalized Medicine to Everyday Practice.
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One Line Pitch:
Bringing personalized medicine to primary practice through pharmacogenetics (PGx) to provide personalized, effective, quicker, and safer therapies.

Project Summary:
Helping providers and patients utilize the benefits of precision medicine through:

- *Direct patient pharmacogenomic counseling service, available to providers and patients, remotely or in person, to provide education, recommendations, order testing, and interpret results*
- *Software based system that guides physicians and educates patients.*

Management:
Yana Vorontsova, PharmD, MBA with the in depth theoretical knowledge of pharmacogenetics
Jason Colasanti, BS in Bioengineering, currently a third year PhD student in Molecular Cell Biology
Isabel Menendez, DVM, PhD, clinician scientist with background in precision, comparative, and translational medicine.
Nicholas Miles, PharmaD with extensive knowledge of clinical pharmacogenetics

End-user Problem:
A provider lacks knowledge and resources to implement pharmacogenetics testing in practice:
Only ⅓ are confident that their training prepared them to work with genetically high risk patients
Only ¼ believed they could find and use reliable information to educate their patients

Target Market:
Pharmacogenomics (PGx) Market Size – USD 5.66 Billion in 2018
Expected to reach USD 11.01 billion by the year 2026, at a CAGR of 8.7%.
"Lowest hanging fruit" niche market will be focused on Primary Care (numbers to quantify)
Our company can scale up by increasing customer numbers (expanding to all US states), as well as expanding to additional markets (i.e. cardiology, oncology, psychiatry, pediatrics)

Customer Validation:
Currently there are pharmacists and labs that provide these services.
Research sponsored by the NIH is ongoing to provide evidence on the utility of PGx in precision medicine.
Scientific publications provide supporting data that PGx improves medical outcomes and decreases health care costs compared to standard of care.

Technology Validation:
There are scientific publications, drug labels, and FDA guidance that validate the benefit of pharmacogenomic testing.
Some of our competitors use validated software with PGx.

Sales/Marketing Strategy:

- *While we are developing the software and app, we will provide PGx consulting through CPA to generate revenue.*
- *We will use our providers to introduce the software and app, to beta-test the software, and to obtain their feedback to finalize and validate the software.*
  We will provide a two month free-trial to new customers for them to try our product and commit to the annual subscription (subscription base model).
- *We will develop collaborations through laboratory contracts to perform the genetic testing.*

Business Model:
Our model provides profits through direct patient management in collaboration with physicians, while also providing revenue from providers that only wish to use our software to aid their practice.
Our company can scale up by increasing customer numbers (expanding to all US states), as well as expanding to additional markets (i.e. cardiology, oncology, psychiatry, pediatrics)

Competitors/alternative solutions:

- *Competition is currently sparse, with no company having a large or considerable share of the market and mostly regional (i.e. Genelex (Invitae), Geneticure).*
- *Individual pharmacists who provide consulting services to their local communities.*
- *PGx software already exists with limited widespread use (i.e. GenXys, YouScript).*

Competitive Advantage:

- *Clinical support from pharmacists specializing in pharmacogenetics*
- *User friendly pharmacogenomic software (Website and App) for providers and patients*
- *Results follow the patients between providers, lowering costs of the healthcare system*
- *Contracting with laboratory to help bring down price for uninsured patients*
- *Software content developed by specialized pharmacists and medical geneticists*

Ethical Risk Assessment:

1. *Our innovation will provide and inform patients about their genetic information. This may be detrimental for the patient's outcome if the information is not interpreted accurately.*
2. *Physicians have time constraints to evaluate patients, are saturated with new information and training through telemedicine, and are constantly making urgent decisions. Each of these could result in the misinterpretation of a patient's pharmacogenetic data. When this data is misinterpreted, it could lead to the unnecessary cessation of medications or unnecessary prescriptions of new medications.*

Several strategies to mitigate these effects:

1. *Provide access to genetic counseling to patients, so that they can have one-on-one guidance and support to discuss their results and what they mean in the overall patient therapeutic plan moving forward. In addition, we can provide brochures targeted to general audiences, detailing common misconceptions about pharmacogenetic tests and their results.*
2. *We will educate, support, and provide guidance to physicians through an onboarding process involving an introductory course on pharmacogenetics and how our innovation process works.*

Risk Assessment:

Risk factor	**Risk mitigation strategy**
Reimbursement	Collaborative Practice Agreement Subscription based model Laboratory contracts
Providers lack of knowledge and wide-spread use	PGx consulting in person/telemedicine by a collaborative team of genetic pharmacists and medical geneticist Educational support through Software and CME
Customer embrace/use of App	Patients will embrace our app by designing a friendly, easy, and convenient app with continuous customer support

Use of Funds:

Source of funds	**Specific activity**	**Funds required**	**Deliverable**	**Delivery by**
Initial funds	Software Development	$100,000		Beta Version Launch: Q4 2021 Version 1.0: Q4 2022
	Marketing	$30,000		Starting Q2 2021
	Personnel Time	$200,00		Starting Q2 2021
	Equipment/Software	$10,000		
	Legal Fees/Licensing	$5,000		
Total initial funds	$345,000			
Subsequent funds needed	**Specific activity**	**Funds required**	**Funding source**	
SBIR	Year 2	$250,000	NIH	
Seed Funding	Year 2-3	$250,000-$500,000		
Total subsequent funds				

Other relevant information:

Financials	Year 1	Year 2	Year 3	Year 4	Year 5
Expenses	$400,000	$600,000	$1,200,000	$4,900,000	$21,000,000
Revenue	$345,000	$500,000	$650,000	$1,1000,000	$2,000,000
Net	$55,000	$100,000	$550,000	$3,800,000	$19,000,000