



We intend to revolutionize the way viruses and bacteria are detected and diagnosed

Guanine Inc. - Business Overview

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Guanine Inc. has developed a handheld electronic sensor that can detect specific viruses and bacteria with PCR accuracy at 25-50% of the cost of lab tests. The pathogen sensor will operate like a glucose sensor and will be sold to businesses and consumers. A suite of infectious disease tests will be developed including COVID-19, respiratory infections, insect-borne infections such as Lyme disease, and sexually transmitted diseases, as well as tests for detecting air, water and food pathogens.

In addition to mobile testing, Guanine has patented artificial intelligence tools for diagnosing infectious diseases that incorporates medical algorithms, rash image recognition and electronic sensor test results. This provides a preliminary diagnosis of having an infection, and directs users to schedule a telehealth appointment in order to confirm the diagnosis and prescribe treatment when the infection is easier and less expensive to treat.

Guanine is seeking \$6 million to develop a COVID-19 test cartridge and mobile reader (i.e. a potentiostat integrating the Analog Devices platform), create a pipeline of qualified customers during test marketing, and generate sales to businesses. A second round will be sought for developing additional tests and AI diagnosis tools targeting consumers. Future expansion will involve the set up, merger or acquisition of an infectious disease telehealth operation in advance of an IPO.

Problem overview: COVID-19 has shown the inability of the centralized lab testing infrastructure to prevent a pandemic from devastating businesses and disrupting human lives. Centralized lab testing takes 1 to 14+ days to identify infected people who can transmit the infection to others while waiting for their samples to be tested. The test consumable cost is marked-up 500% or more to cover costly laboratory overheads and labor-intensive services for collecting, transporting, preparing, testing and reporting test samples. Centralized testing causes lost productivity when employees and consumers travel to test centers and doctor appointments for test requisitions, sample collection and/or test results.

Mobile testing technologies including portable PCR, isothermal amplification and antigen tests do not detect positive patients as much as 1/3 of the time allowing infected people to transmit the infection to others. Antigen tests misdiagnose negative patients up to 1/3 of the time which needlessly isolates healthy people. COVID-19 is expected to remain in the population for years, mutate into new infective strains, and cause further diagnostic challenges. Many more pandemics are expected based on a UK Government report projecting that deaths from antimicrobial resistant bacteria will exceed cancers by 2050 including a portion of the 2 billion people currently infected with latent tuberculosis where 10% can become active during their lifetimes.

Breakthrough in pathogen detection: Guanine Inc. has developed an electronic pathogen sensor that accurately detects low concentrations of viruses and bacteria without a lab, similar to a glucose sensor. Target viruses and bacteria are bound to millions of electrical detection tags that produce a burst of electrons when voltage is applied. The sensor measures the electrical current and converts the signal to a digital concentration level that can be displayed in minutes and transmitted to a user file. Guanine's electrical signal amplification method attaches millions of electrical tags and eliminates the need for replicating millions of copies with PCR or time-intensive cultures which are subsequently detected with insensitive optical tags.

Breakthrough in infectious disease diagnosis: Guanine Inc. has patented an AI tool for diagnosing infectious diseases by incorporating medical algorithms, rash image recognition and electronic sensor pathogen detection. This provides a real time diagnosis of various infections, and helps users understand the urgency of seeing a doctor. An AI assessment algorithm will query users about symptoms, history, exposure to sources of infection, and import information from other databases. If a rash is present, a photo can be uploaded for analysis using image recognition. If appropriate, specific Guanine tests will be sent to the user for detecting pathogens and/or antibodies. An AI diagnosis algorithm characterizes the basic inputs along with test results and uses the most current guidelines for ruling in or ruling out infections, and scoring the diagnosis accuracy. The preliminary diagnosis and test results will be produced along with supporting factors and recommend whether the user should urgently see a doctor, get repeat testing at a later time or do nothing. When appropriate, users are directed to schedule a telehealth appointment in order to confirm the diagnosis and prescribe treatment at a considerable time and cost savings over traditional tests and assessments. Algorithms will be prepared from medical guidelines with inputs from infectious disease specialists and updated regularly as new guidelines are created. Results from multiple users can be automatically assessed to identify outbreaks and new rules for improved diagnosis.

Steps for Commercial Scalability: The steps needed for commercial scalability for the business market involve: (1) rework an existing RNA test to detect COVID-19, optimize the assay for nasal and throat samples, and validate the assay with patient samples at an IRB approved facility with a diverse study population in advance of seeking emergency use authorization, (2) integrate the Analog Devices (ADI) potentiostat platform with off the shelf components into a handheld device and operate the test processes in a single use electronic sensor cartridge, (3) outsource the manufacturing of the instrument and cartridge, and (4) create a direct sales team to sell the COVID-19 solution to businesses.

TEAM

Organization: The team will address (1) product development, (2) test marketing with beta test units to validate the product and develop a sales pipeline for business customers, and (3) launch the product with direct sales and online sales to businesses. Assay development will initially be directed by Neil Gordon and Garry Palmateer, and then be assigned to a senior assay developer. Product development will be overseen by Steve Rock. Neil will move into test marketing and build a sales and marketing team that will be headed by a new hire. Ara Altounian is the head of operations, and Raj Bawa is the chief intellectual property officer.

Neil Gordon, B.Eng./MBA – President/Founder has over 30 years experience in product development, marketing and corporate management. He was one of the one of first business consultants in nanotechnology and specialized in the convergence of nanotech, biotech, and infotech. He headed commercialization for the NASA-led CANEUS Micro and Nanotechnology consortium for aerospace and defense industries, and spun out a company from NASA's Ames Research Center to commercialize NASA's carbon nanotube electrochemical sensor then built an automated testing instrument for detecting RNA from bacteria and viruses. He subsequently invented and patented the quadruplex detection tag, the mobile electronic sensor, and AI diagnosis platform. Neil has previous experience developing an expert system for predicting winning bid prices, commercialized a queuing model with sensors for staffing tellers, marketed prototyping systems for cockpit design and flight simulators, and oversaw outsource manufacturing of PC graphic cards.

Steve Rock, PhD EE/ME - VP Product Development is a research engineer with over 25 years experience and specializes in product development and manufacturing. Steve has built prototypes of the electronic sensor and developed preliminary versions of the cartridge. He is configuring the instrument components and will direct the development of the cartridge, instrument and software.

Garry Palmateer, MSc (Biology) - VP Assay Development is a microbiologist with over 40 years experience in detecting bacteria and viruses. Garry previously operated pathogen testing labs for the Ontario Government and in the private sector, oversaw remediation of the Walkerton E.coli outbreak, and co-developed the sensor and testing instrument in the predecessor NASA spin-off company. Garry will independently review test compliance, apply controls and standards to the assays, and assist with all protocols including new applications.

Ara Altounian, B .Eng, MBA - VP Operations has over 35 years of diverse experience in engineering, retail, software design and instruments, and previously worked with Neil in three companies. Ara will oversee administrative and support duties.

Raj Bawa, PhD (Microbiology) - Chief Intellectual Property Officer is an authority on nanomedicine, a patent agent who formerly worked at the USPTO and is a board member of Guanine. Raj is Guanine's chief IP officer and assists with patents and strategic direction.

MILESTONES/FINANCIALS

Projected 24-month Income Statement by Quarter: The 24-month projection is driven by: (1) a 15 month window to complete development and being marketing the COVID-19 test to businesses, (2) a 24 month window for attain 18 business customers in the US that test employees and/or customers daily, and (3) a cartridge unit cost of \$21.

Income Statement	Yr 1				Yr 2			
	Y1-Q1	Y1-Q2	Y1-Q3	Y1-Q4	Y2-Q1	Y2-Q2	Y2-Q3	Y2-Q4
Business Sales	0	0	0	0	0	72	261	620
Consumer Sales	0	0	0	0	0	0	0	0
Revenue	0	0	0	0	0	72	261	620
Cost of Goods Sold	0	0	0	0	0	43	156	267
Margin	0	0	0	0	0	29	106	353
Research & Development	310	310	352	430	440	440	440	440
Sales & Marketing	0	0	69	176	251	276	276	276
Operations, General & Admin	94	94	114	140	150	150	160	160
EBIDT	-404	-404	-535	-746	-841	-837	-770	-523
Interest - Long Term Debt	0	0	0	0	0	0	0	0
Interest - Working Capital	0	0	0	0	0	0	0	0
Depreciation	0	2	0	7	0	0	0	20
Earnings Before Income Tax	-404	-406	-535	-752	-841	-837	-770	-542
Taxes	0	0	0	0	0	0	0	0
Net Earnings	-404	-406	-535	-752	-841	-837	-770	-542

Projected 5-year Income Statement: The 5-year projection is driven by: (1) attaining 1,500 business customers in the US and internationally, (2) retaining existing business customers with cloud user files containing infectious disease histories and symptoms, (3) expanding business use with respiratory tests for multiple infections (COVID, influenza, TB), developing tests for air (Legionella), water (E.coli) and food (norovirus), (4) attaining 50,000 consumer users with a lower priced test reader, (5) developing consumer tests for insect bite infections (Lyme, West Nile) and sexually transmitted diseases, and (6) enticing consumer users with free online AI assessment tool. The key element of the business model is the volume sale of single use test cartridges. The low price of the instrument will initially be used as a loss leader. The user database/AI modules can build user loyalty. Portions of the AI assessment module can be offered as a free online tool to assess consumer symptoms including photos of rashes associated with Lyme disease and sexually transmitted diseases while collecting contact information and recommending what infections to test for.

Income Statement	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5
Business Sales	0	953	20,384	61,468	108,506
Consumer Sales	0	0	443	6,832	87,181
Revenue	0	953	20,827	68,300	195,686
Cost of Goods Sold	0	466	7,746	19,852	51,515
Margin	0	487	13,080	48,448	144,171
Research & Development	1,401	1,760	6,422	11,395	16,094
Sales & Marketing	244	1,078	3,583	6,630	16,272
Operations, General & Admin	443	620	2,525	4,869	6,999
EBIDT	-2,088	-2,970	549	25,554	104,806
Interest - Long Term Debt	0	0	0	0	0
Interest - Working Capital	0	0	0	0	0
Depreciation	9	20	20	76	178
Earnings Before Income Tax	-2,098	-2,990	530	25,477	104,628
Taxes	0	0	0	8,917	36,620
Net Earnings	-2,098	-2,990	530	16,560	68,008

Company status: Guanine IP is currently protected by two approved patents and a pending patent. Assays were previously developed to detect drug-resistant *Klebsiella pneumoniae* carbapenemase RNA in urine, and *E.coli* RNA and *cryptosporidium* surface membrane proteins in water. The management team is in place, a development lab with assay development equipment is in place, the test protocol has been validated. Development plans have been made for a COVID-19 RNA assay in a NIAID grant application, for an AI tool with pattern recognition for Lyme disease Erythema migrans rash recognition in a NSF grant application. The test cartridge and the handheld reader have been specified, and the electronic sensor has been prototyped.

Funding Rounds: Guanine is seeking an investment of \$6 million to cover 24-month costs. This will provide sufficient reserve funding in the event that development requires more time or that sales are delayed. An additional round is expected in year 3 to finance the development of additional tests, pursue the consumer market and international sales.

MARKET/COMPETITION

Market: Infectious disease testing is a \$60 billion market made up of about \$15 billion from test reagents and about \$45 billion from testing services (i.e. labor associated with collecting, transporting, preparing and testing a sample, assessing and diagnosing the patient, laboratory overhead, G&A and fees). Based on an average price per test of \$100, there are approximately 600 million tests per year. Developed nations make use of highly accurate tests conducted in biosafety labs (85%), and moderately accurate point of care (POC) tests in CLIA labs such as clinics (15%). Consumer tests (<1%) are often limited to sample collection kits that are shipped to a lab for processing. Testing in developing countries make use of low cost tests that are not very accurate despite being the disproportionate source of most infective pathogens such as COVID, TB, malaria, cholera and Ebola.

Addressable market: The addressable market for Guanine's mobile pathogen testing systems and AI diagnosis tools is businesses and consumers who want to test themselves in-house for COVID-19 and other pathogens. Millions of businesses and consumers have suffered great losses from the COVID-19 pandemic. In addition to reassuring themselves, their employees and their customers about being COVID free, target customers want to take control of their ability to test themselves for COVID-19 and other pathogens. The addressable market includes: (1) Businesses with skilled employees who work and/or live in close proximity (food, mining, oil, chemical, paper, engineering-construction, military contractors, utilities, high end gyms), (2) Businesses with high risk residents living in close proximity (Nursing homes, Elder care communities/condos) (3) Educational Institutions with students paying high tuition to attend university or private schools and/or live in close proximity (In-person teaching, dormitories, research labs, sports teams), (4) Businesses that sell high value hospitality stays (Cruise ships, all-inclusive resorts, casinos), (5) Businesses that sell high value products in-person (Car dealers , realtors), (6) Individuals who are high risk of dying from an infection (People with weakened immune system from transplants, cancer treatments, HIV/AIDS); people with pre-existing lung problems (COPD), lung cancer, cystic fibrosis, asthma, smokers, vapers; Older adults; People with heart disease, diabetes and obesity) (7) Individuals who care for or live with high risk individuals; (8) Individuals who live in isolated areas with limited access to healthcare, (9) Individuals who want to control their own healthcare decisions;,(10) Individuals who are health conscious, (11) Individuals who lack health insurance, and (12) Individuals exposed to reckless behavior.

Competitive positioning: Guanine will disrupt the centralized laboratory testing services market by enabling users to eliminate the disproportionate testing service cost with a do-it-yourself testing system that matches the accuracy of lab tests. Businesses and consumers will benefit by: (1) taking complete control and privacy to test whenever they want and how frequently , (2) getting test results in 15 minutes of sample collection instead of waiting 1-14+ days for results, (3) accurately testing their employees, customers or themselves with minimal lost productivity, (4) storing their test results and symptoms online for future reference and proof of being infection free, (5) accessing an AI tool to select the most appropriate pathogens to test for and rapidly find out if a doctor should be urgently seen, and (6) getting tested at 25-50% of the price of a lab test once a reader is purchased.

Product offering: The preliminary offering will comprise: reader at \$495 for businesses and upgradeable limited function reader at \$199 for consumers, test cartridges starting at \$49 and user software AI licenses at \$99/year/node which is free for the first year for consumers. The software license will provide password protected cloud storage for test results, symptoms, and medical history, with access to the AI modules and frequent updates when new guidelines are produced.

Business buying characteristics: Target business purchasers of in-house testing include: (1) businesses that have been directly impacted by a COVID-19 infection or COVID-related business losses, and (2) businesses that are situated where

hospital testing and/or commercial testing is difficult to obtain or has a long wait time. These businesses will be identified by Guanine lead generation, telemarketing, direct mail or email directed to key staff, and by PR such as mobile billboards situated near drive-through sample collection centers. Internal sales people will contact active leads. Promotional activities can include a free trial of the test reader with 10 complementary COVID-19 test cartridges. Free systems will be provided to key companies and internet influencers in exchange for testimonials.

Consumer buying characteristics: Target consumer purchasers of in-house testing include: (1) consumers that are expected to have been impacted by a COVID-19 infection directly or from a family member, (2) consumers that are searching for COVID testing information on the internet, (3) consumers that are tech savvy, (4) consumers having access to hospital testing and/or commercial testing that is difficult to obtain or has a long wait time, and (5) consumers that may be inconvenienced by or mistrust traditional healthcare. These consumers will be identified by social media ads, and by mobile billboards situated near drive-through sample collection centers or clinics. These consumers will be enticed by a free online module of the AI system to help them assess their symptoms and educational information supplied on the Guanine website. Promotions can also include free readers to influencers, key groups and community organizations such as churches.

Competitors: Virtually all COVID-19 test suppliers sell their tests exclusively to testing service organizations such as hospitals, government labs, commercial labs and healthcare clinics with limited brand awareness to consumers about the vendor being used for PCR. These lab testing service organizations are viewed by businesses and consumers as competitors to self testing. Many testing service organizations employ high throughput equipment vendors with proprietary reagents (Roche, Danaher, Abbott, and Siemens) and will either ignore Guanine or use negative opinions to downplay Guanine's benefits. Commercial lab testing services such as Quidel and LabCorp have developed home sample collection kits for COVID-19 that need to be sent back to their labs for processing. Commercial labs are expected to increase their home sample collection options. Point of Care (POC) equipment vendors (Abbott, Cepheid) will likely improve the technical performance of their systems with better optical readers and improved temperature controls in order to reduce their false negative rates which can be as high as 33% of tests. Some POC equipment vendors will reduce the cost of readers (Abbott ID Now price is \$10k) but will continue to sell to CLIA labs such as clinics and physician office labs (POL) to avoid cannibalizing their customer base. Home antigen tests will become increasingly available and some vendors may make false claims about their accuracy. None of the testing service organizations are expected to severely drop their service prices of \$100-\$200+ for PCR to match Guanine's test price.

Collaborators: Guanine will pursue partnerships with (1) infectious disease specialists who are renowned experts with viral and bacterial infections, and will assist in developing and promoting associated tests and the AI modules in exchange for a sales commission, (2) strategic development labs that have patient samples and facilities for specific viruses or bacteria, (3) one or more telehealth firms to exchange leads for testing and diagnosis, (4) health insurance companies who can potentially reimburse their members for Guanine tests, and (5) contract manufacturers who can decrease the unit cost of test cartridges and readers.

Risks: Guanine's principal risks include the following: (1) The test doesn't attain PCR accuracy. Guanine has developed a suite of technologies that can maximize the pathogen detection signal, minimize interference from non-specific materials, and minimize background noise to improve the detection performance and accuracy. (2) The test cartridge and reader will take longer to develop. Guanine has previously developed an RNA assay and will reuse the protocol to get a baseline COVID-19 assay within 2 months. The test cartridge and instrument will be rapidly prototyped and using off the shelf components to reduce development time and risk. (3) The test encounters great resistant from the testing service establishment which will delay initial sales. Guanine can shift sales in the short term to unregulated applications (research use, military, international). If necessary Guanine can alternatively license or sell the platform for non-human pathogen testing such as research animals, veterinarians, pharmaceutical production, food, and water and target companies in key verticals. (4) Competitors develop their own electronic sensors. Commercial electrochemical sensors do not attain the accuracy required for clinical pathogen testing without signal amplification. Companies employing nanosensors (e.g. Guanine's predecessor) encounter high fabrication cost and poor production yield that make the nanosensor financially unfeasible. Competitors may employ the oligonucleotide detection tags but risk infringement of Guanine's patents. Guanine also has developed a series of trade secrets which can deter copycats from attaining similar technical results. Guanine will also differentiate its tests with AI tools and sell its reader for a low price.