APTAVID

A molecular detection **platform**

Product Pipeline:

COVID | Common cold
Influenza | Pneumonia
Strep | More…

Introducing Aptavid

- Rapid and Accurate results
- Cheap to Mass Produce
- Emerging Home Use Strategy

COVID-19 Testing

252

FDA
EUA Issued

237

Laboratory
Based Tests

15

Point-of-care tests
for use by healthcare
professionals

6

Require
machine readers

0

Rapid tests for home use not requiring a prescription available now

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Flow Through Testing

Our individualized tests are sealed for protection to ensure a longer shelf life. The flow through method enables end users to add a larger amount of saliva with inherently greater viral load, which increases test accuracy and results are achieved faster than traditional lateral flow.

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End User Safety

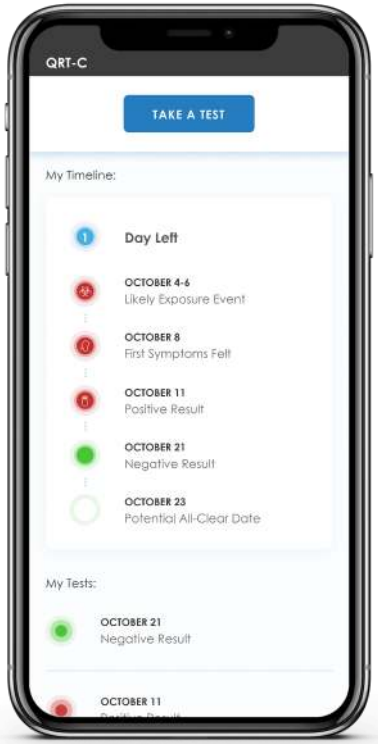
The purposefully designed funnel attachment securely attaches to the cassette reducing any potential fluid contact with the end user.

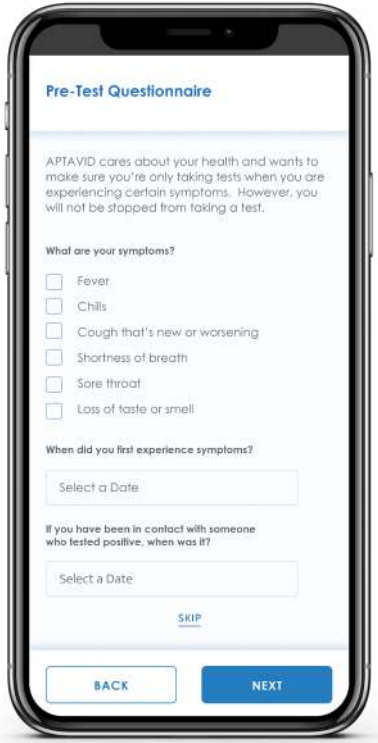
The vials are inserted into the funnel with the hermetic seal being punctured and fluid flowing down and into the test strip.

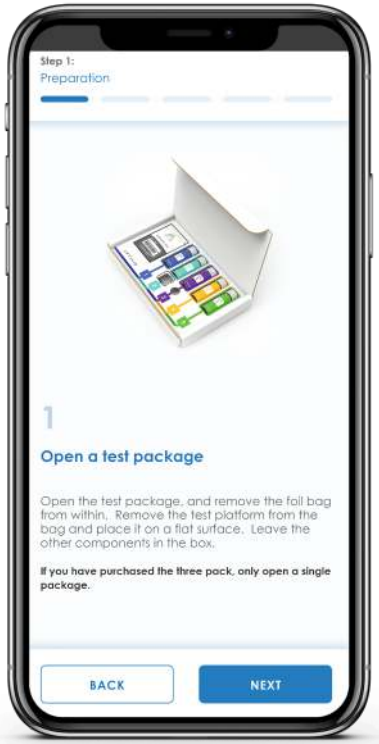
Fully Accountable Ecosystem & Application

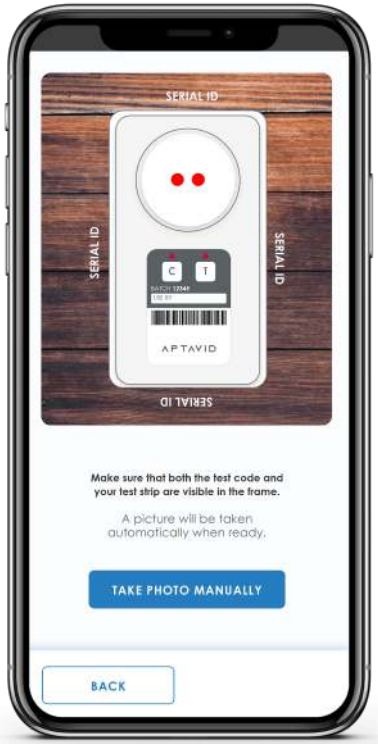
The application is the guide to the user and a link to healthcare professionals. Users are guided through the steps of the testing process and given reassurance, and valuable information throughout the process.

A fully traceable experience - each test has a unique serial number linked with the application.









	Aptavid Surface Test	Aptavid At-home	Cue Health	Ellume	Abbott Binax Now	Access Bio –CareStart	Quidel Sofia
Use Type	**Surfaces**	**At-home**	At-home	At-home	At-home	Healthcare professional	Healthcare professional
Collection method	**Surface**	**Saliva**	Nasal swab	Nasal swab	Nasal swab	Nasal swab	Nasal swab
Technology	Colorimetric assay	Flow-through	Nucleic acid isothermal amplification	Lateral flow	Lateral flow	Lateral flow	Lateral flow
Machine reader	**No**	**No**	No	No	No	Yes	Yes
Time to results	**5 minutes**	**5 minutes**	20 minutes	15 minutes	15 minutes	10 minutes	15 minutes
Limit of detection*	10-100 $TCID_{50}$/mL	10-100 $TCID_{50}$/mL	20 genome copies/wand	10,000 $TCID_{50}$/swab	22.5 $TCID_{50}$ per swab	800 $TCID_{50}$/mL	417,000 $TCID_{50}$/mL
Sensitivity/Positive Percent Agreement	TBD	TBD	99%	95%	84.6%	83.33%	96.7%
Cross reactivity	TBD	TBD	98%	Bleach	MERS-CoV, coronavirus HKU1	None reported	None reported
Cost per test to consumer/Insurance	**$5 - $15**	**$5 - $15**	TBD	$30	$20-$100	$20-$100	$75 - $150

*Aptavid Limit of Detection (LoD) range conversion from virus particles per mL to $TCID_{50}$ standard calculated using the following sources

a) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7198196/
b) https://www.atcc.org/support/faqs/48802/Converting+TCID50+to+plaque+forming+units+PFU-124.aspx

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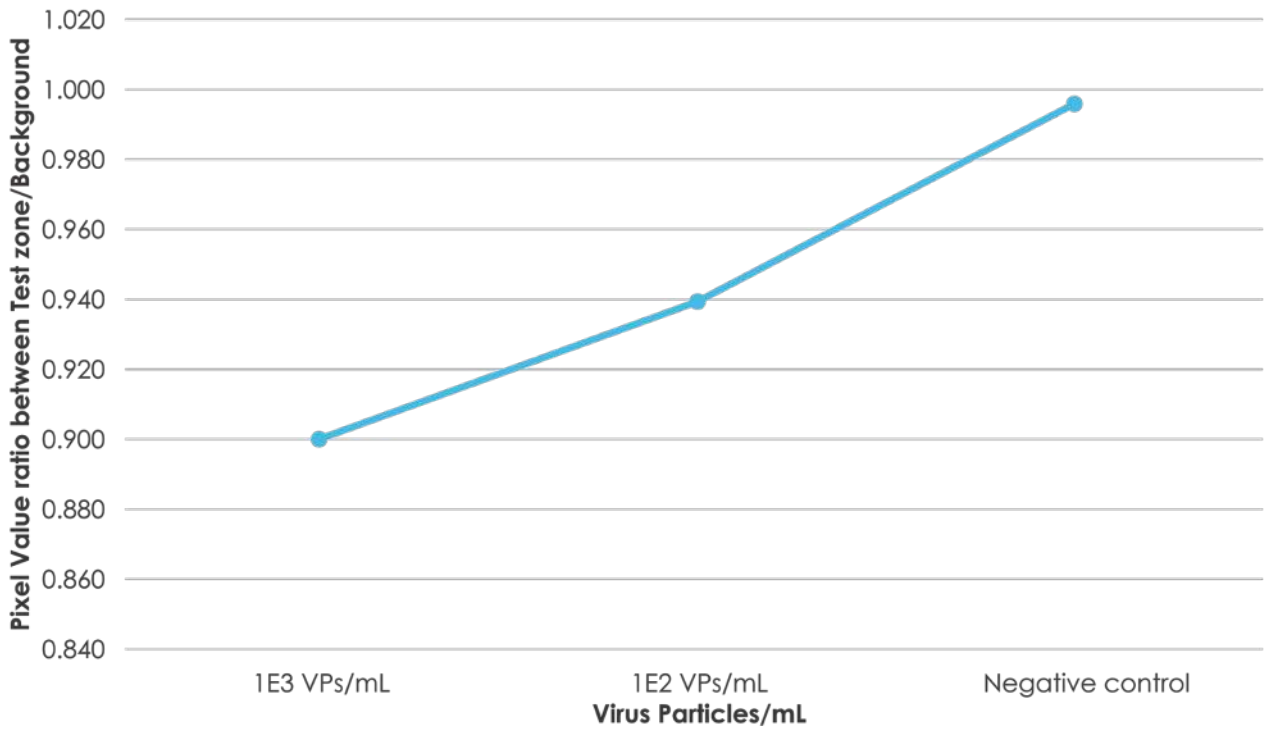
Aptavid Limit of detection results as sensitive as PCR benchmark!

Expectation*
>99% sensitivity
>99% specificity

Virus Particles/mL	Average pixel value (Test Zone)	Average pixel value (Background)	Ratio between Test zone/background
1E3 VPs/mL	176.756	196.309	0.900
1E2 VPs/mL	187.170	199.338	0.939
Negative control	210.821	211.655	0.996



* Aptavid is in the process of setting up FDA recommended evaluation studies to determine formal sensitivity and specificity rates. Complete data package available in Aptavid Data Room.

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Scalability

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- Oligo DNA synthesis is inexpensive and relatively fast to manufacture
- There is an established industry for DNA synthesis
- 2-5 cents per test

100:1

Abbott Binax

- It is challenging to manufacture antibodies. The process requires expression in mammalian cell culture
- Bill Gates has been quoted saying that scaling up antibody production is one of the open challenges facing humanity

Executive Team

Daniel Roth, CEO

After growing up in Jerusalem and then Long Island, Daniel Roth attended Trinity College in Hartford, CT, and graduated with a degree in biology. He began his career in a 2-year analyst program at Commonfund Capital in CT, then a $6B private equity fund of funds (now $15B) that exclusively manages the investments of nonprofit and educational institutions.

He then became an analyst at AGT International, a company that provided security and intelligence solutions post 9/11. He helped multiple US and international intelligence agencies and departments of defense build strategic defense assets using Israeli government owned technology, and in partnership with large US defense contractors.

During this time, Daniel was also involved with the Arab-Israeli peace initiative Bridging the Rift, a joint project of Stanford, Cornell, Prime Minister Ariel Sharon of Israel, and King Abdullah of Jordan.

In 2009, Daniel received his MBA from the Interdisciplinary Center in Herzliya, Israel. At that time, he started an Internet software marketing company called Easy.ly, which got acquired by Aspire Rock, where he worked from 2011-2017.

With the freedom afforded to him by the acquisition of Easy.ly, Daniel followed his passions in studying the singularity as a development in the future of technology. He became a connector in the singularity community, organizing talks for top American AI researchers and governments around the world.

During this time, Daniel also became passionate about the potential of CRISPR gene-editing technology and started an initiative to ensure that this technology was developed and distributed fairly, with access available to diverse groups.

When the COVID-19 pandemic began, Daniel guided the formation of Aptavid's founding team with a vision to create a test that required no personnel to administer, no hardware, could be done at home, took 5 minutes to get results, and cost under $5.

As co-founder and CEO of Aptavid, Daniel is motivated to help bring the COVID-19 pandemic under control, and build a customizable molecular detection platform in a post pandemic era, that serves one billion people around the world.

Executive Team

Russel Hanson, CSO

After earning his M.S. in Biology from Georgia Tech and his Ph.D. in Computational Chemistry from Boston University, Russell researched and taught biomedical informatics as a postdoc at numerous institutions, including MIT, Harvard University, Harvard Medical School, the Boston Children's Hospital, and the Center for Biological Sequence Analysis at the Danish Technical University.

In 2014, Russell became an Assistant Professor at the Icahn School of Medicine at Mount Sinai, within the Department of Genetics and Genomic Sciences. He worked on molecular engineering, cancer vaccines, cancer sensors, synthetic biology, molecular sensors, aptamer sensors, imaging, biophysics, nanotechnology, neuroscience, connectome imaging, bioinformatics, genomics, personalized medicine, stratified medicine, and biomarker development.

When the COVID-19 pandemic began, Russell and his team started writing grants for research on an aptamer test for the active virus. Their vision was to create a test that required no personnel to administer, no hardware, could be done at home, took 5 minutes to get results, and cost under $5.

Testing with aptamers, as opposed to testing for antibodies, was the key strategy that allowed the team to realize this goal. Their research into COVID-19 aptamers also allowed them to create the first at-home surface test for the virus that provides instant results.

Beyond helping to create a powerful tool to aid in the immediate pandemic, Russell's broader commitment has been to empower individuals with precise data about their health. After working in biomedical informatics and technology for the last 15 years, Russell's work with Aptavid--along with his research towards his second Ph.D., in Bioinformatics--continues his passion for using synthetic biology to solve fundamental problems in human health.

Executive Team

George Botos, Director

After graduating with an undergraduate degree in chemical engineering and an M.S. in synthetic chemistry from Politechnica University of Timișoara in Romania, George Botos worked in R&D at a disinfectant company later acquired by Proctor & Gamble.

In 2001, he emigrated to Canada, and studied at the Toronto Institute of Pharmaceutical Tech, receiving a diploma in pharmaceutical R&D. He then worked at a Canadian company making disinfectants. He rose from supervisor to R&D manager to technical director, managing a team of microbiologists working on testing protocols.

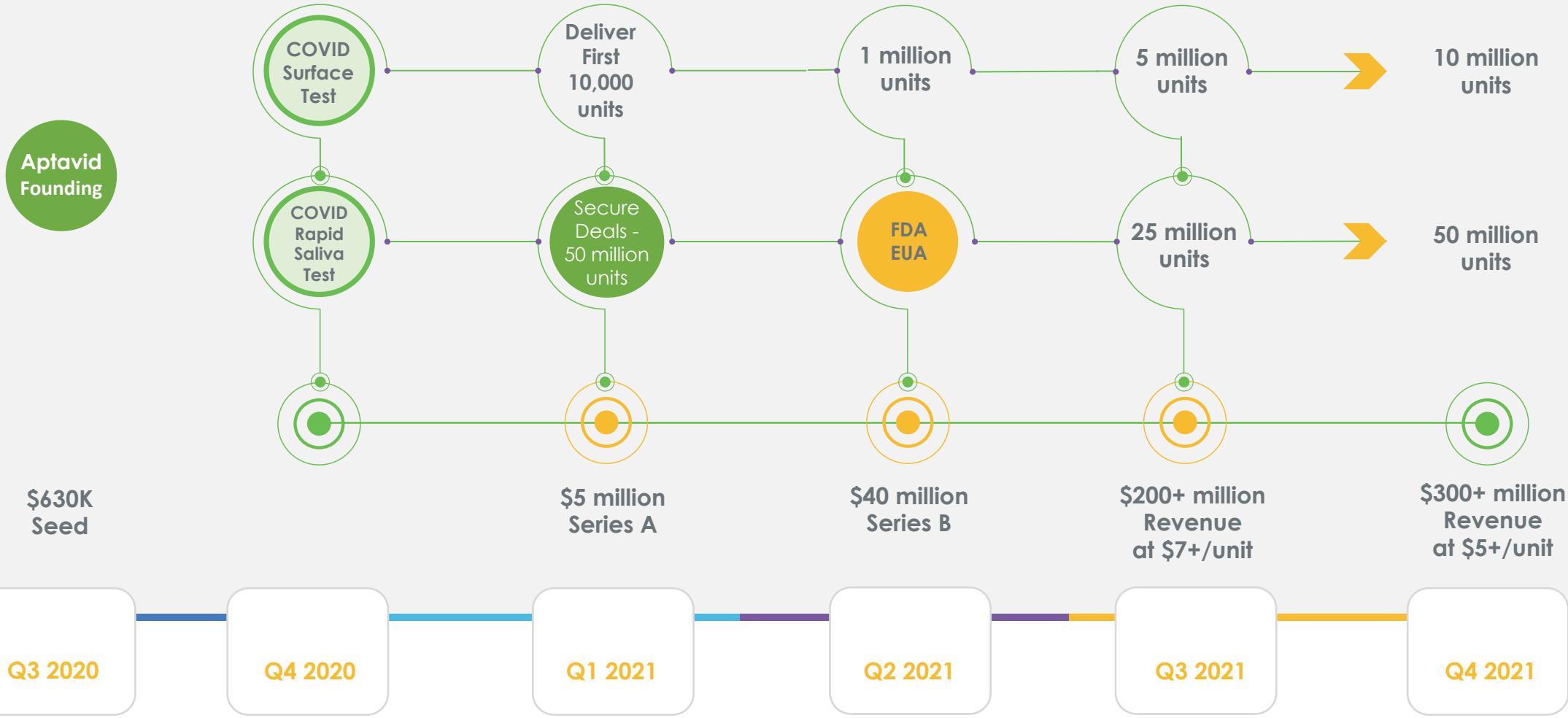
George received his MBA from the Schulich School of Business at York University, focusing on healthcare management. He became a life sciences market research analyst at the MaRS Discovery District, an incubator partially funded by the Canadian government to help Canadian start-ups.

After George's work at MaRS, he used his expertise in disinfection to co-found a company that created rapid-sterilizing systems using ozone and high-frequency ultrasound for dental applications. He then worked with the University of Waterloo to help validate a new technology using functionalized gold nanoparticles to detect microbes in water.

Together they created Genemis Laboratories, which developed this technology into a water testing product for the dental market. Genemis has been doubling or tripling every year since 2014, and is now the main supplier of water test kits for the dental market in Canada. They have since expanded in the U.S. and Canada, creating products that test for bacterial contamination in commercial pools, cooling towers, hotels, and for home use.

Now as Director at Aptavid, George is thrilled to be using his expertise in functionalized nanoparticles for microbial testing, to help create one of the most important testing applications in recent memory: rapid at-home surface testing for COVID-19. He is also excited to expand Aptavid's technology to become a universal, flexible platform for testing for all viruses in home and environmental applications.

Launch/Revenue Plan



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Manufacturing Partners

COVID Human Diagnostic

Drummond Scientific
- Abbott and Roche are customers
- 1 million units per month capacity
- US based

Web Industries
- Largest global test strip manufacturer
- 10 million units per month capacity
- US based

Indo-MIM
- Aptavid seed investor
- <$1 cost per unit
- India based

COVID Surface Test

Argonaut
- 1 million units per month capacity
- US based

Genemis Laboratories
- 200,000 units per month capacity
- Canada based

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Business Development Strategy

1 Low hanging fruit

Example: Aptavid presented to the US Department of Defense and they are interested with FDA EUA

- US Department of Defense
- UAE conglomerate responsible for vaccine program
- Germany Federal Ministry of Health
- Other governments

2 Corporate branded COVID tests

Example: The W Hotels rapid COVID Test (powered by Aptavid)

- Distributor with 100+ salespersons to to reach Fortune 500 executives
- Corporate relationships with Fortune 500 companies

3 200+ Distributors

Example: Distributor with 70+ salespersons

- Sell to hospitals, clinics, pharmacies, schools and more

4 Advanced retail development

Example: In communication with decision makers at Walmart

- Walmart
- Sam's Club
- BJ's

5 Home use & Consumer brand

Reach consumers online through affiliate marketing. Example: Commission Junction, a top US based affiliate network

- Online affiliate marketing
- App marketing with AppsFlyer

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Corporate Customers of Distribution Relationships

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Now raising

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Series A Investment

$ 5,000,000

Use of Proceeds

Finalize test kit	
Pre-production protocol transfer	75,000
Industrial design	25,000
App design & development	150,000
	250,000
Regulatory	
Studies:	
Limit of detection	75,000
Clinical evaluation	300,000
Cross reactivity studies	50,000
Usability study	150,000
Flex studies	50,000
Reagent stability studies	50,000
Regulatory consulting	75,000
	750,000
Production	
Surface test kits	500,000
Human diagnostic test kits	2,500,000
	3,000,000
Selling, General & Administrative	
Executive Management	300,000
Marketing & PR	100,000
Business Development	150,000
	550,000
Legal & Professional Services	**200,000**
Total	**4,750,000**

Bring the most accurate rapid COVID saliva test to market and save lives

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Series B Investment

$ 40,000,000

Use of Proceeds

Production	
COVID Surface test kits	3,000,000
COVID Human diagnostic test kits	25,000,000
	28,000,000
Expand product offering	
R&D:	
Common cold	500,000
Influenza	500,000
Streptococcus	500,000
App	500,000
	2,000,000
Regulatory	
Studies:	
Limit of detection	200,000
Clinical evaluation	1,000,000
Cross reactivity studies	100,000
Usability study	500,000
Flex studies	150,000
Reagent stability studies	150,000
Regulatory consulting	300,000
	2,200,000
Selling, General & Administrative	
Executive Management	1,000,000
Marketing & PR	2,000,000
Business Development	2,000,000
	5,000,000
Legal & Professional Services	**500,000**
Total	**37,700,000**

Scale production and expand product offering

Regulatory Advisors

USA

FDA

Dr. Timothy Stenzel

Director, Office of In Vitro Diagnostics and Radiological Health at the FDA. Advises Aptavid on weekly FDA Virtual Town Hall Series - Coronavirus Test Development and Validation.

NDAP

NDA Partners LLC

Dr. Alberto Gutierrez

25 years at the FDA, 17 years working in In Vitro Diagnostics. Responsible for illuminating the truth on Elizabeth Holmes and Theranos product. Advises Aptavid on final FDA submission.

Potomac LAW GROUP

Dr. Jur Strobos

30 years providing regulatory consulting to companies that manufacture, import, or sell medical products, regulated by the US Food and Drug Administration (FDA). Advises Aptavid on strategic regulatory matters.

Cooley

Natasha Leskovsek

Advises medical device and biotechnology companies on US FDA regulatory and clinical development matters. Advises Aptavid on product marketing.

International

EMERGO by UL

APTAVID

A molecular detection **platform**

Vision

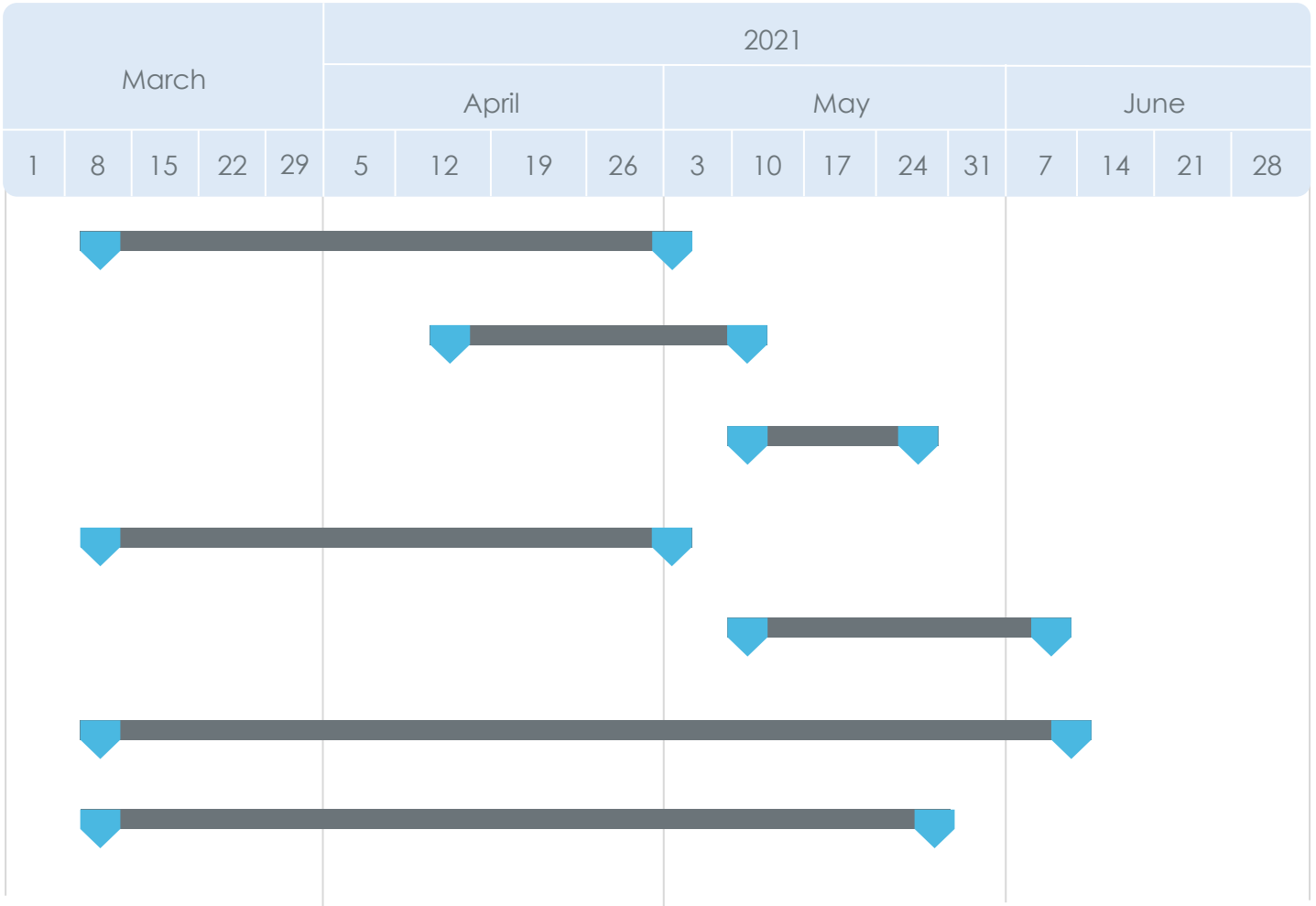
To see humans live active, confident, happy, connected lives

Serve one billion humans

Appendix

Aptavid COVID EUA Schedule

ID	Task Name	Duration
1	Final Pre-production Optimization	41 days
15	Pilot MFG	21 days
20	EUA verification inhouse	12 days
29	EUA pre-clinical action	41 days
32	EUA VER clinicals	22 days
36	EUA submission	70 days
43	EUA stability program	60 days



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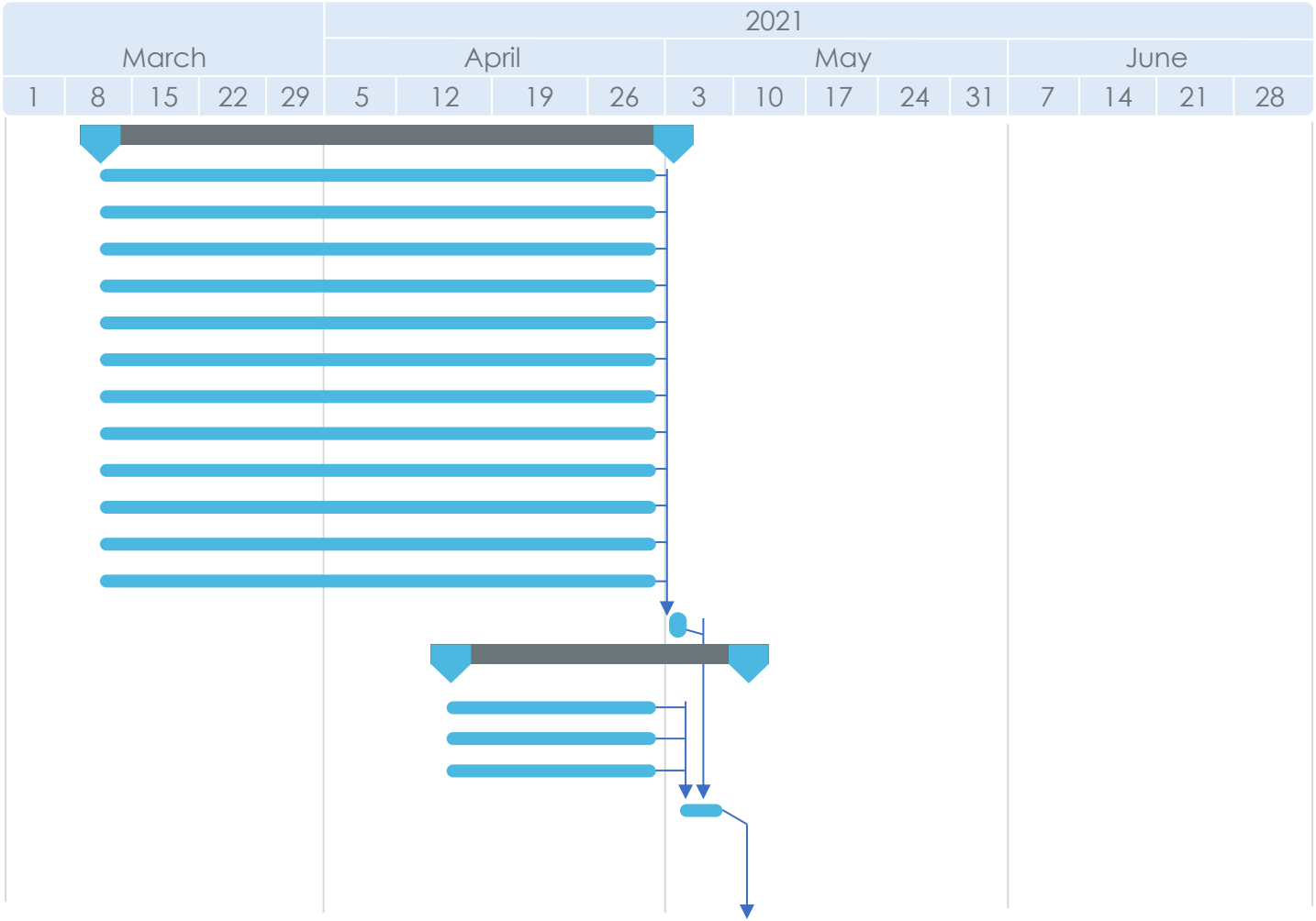
Aptavid COVID EUA Schedule

ID	Task Name	Duration
1	**Final Pre-production Optimization**	**41 days**
2	Optimize aptamers	40 days
3	Optimize capture formula	40 days
4	Optimize detector formula	40 days
5	Optimize control line	40 days
6	Optimize sample proc rgts	40 days
7	Optimize wash	40 days
8	Optimize detector soln	40 days
9	Optimize substrate soln	40 days
10	Optimize pads	40 days
11	Optimize plastic	40 days
12	Optimize sample collection	40 days
13	Optimize rgt vials	40 days
14	EUA DEV design review	1 day
15	**Pilot MFG**	**21 days**
16	Pilot materials	10 days
17	Pilot plastic	10 days
18	Pilot MCPs	10 days
19	Pilot MFG	5 day



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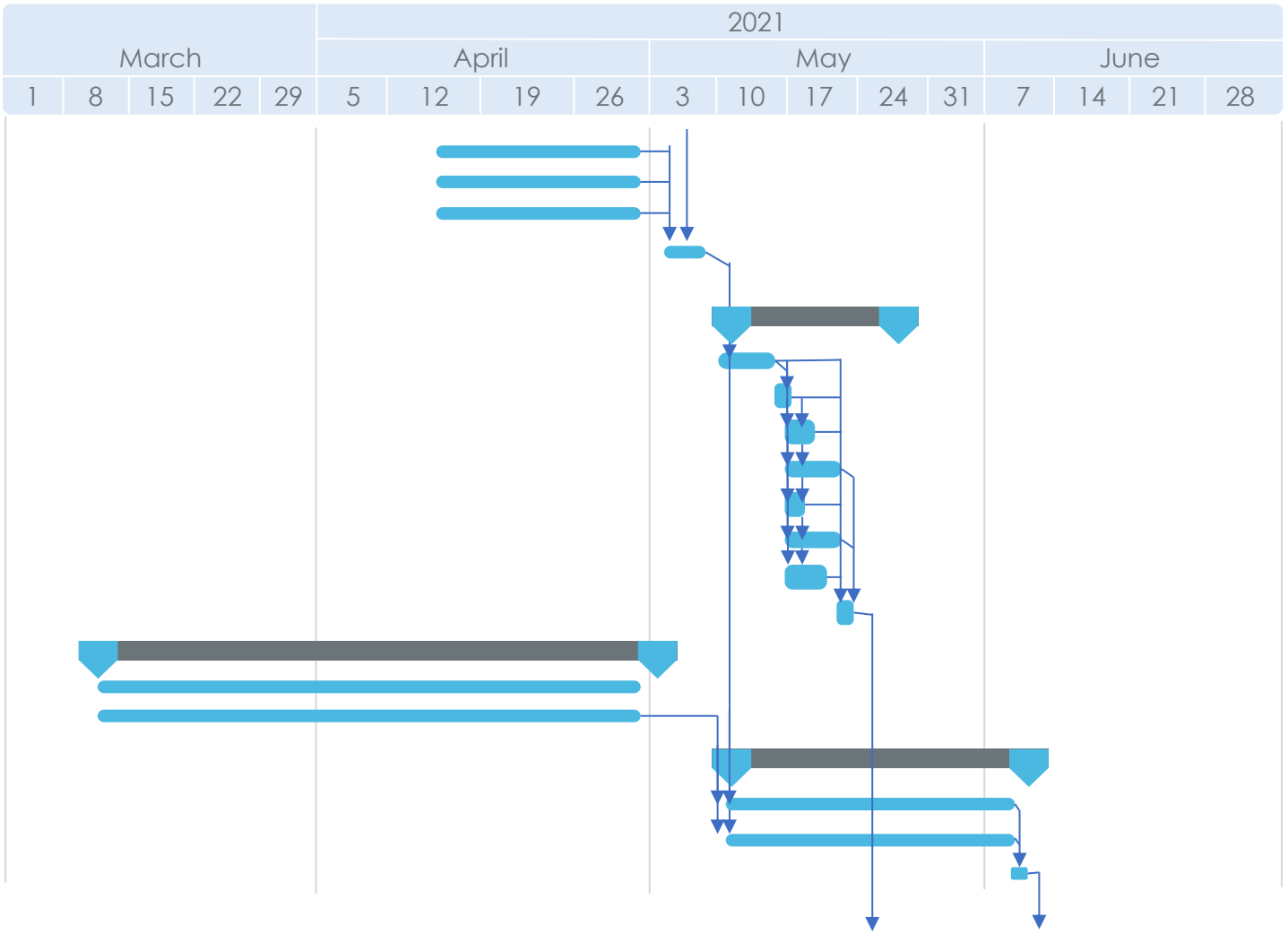
Aptavid COVID EUA Schedule

ID	Task Name	Duration
16	Pilot materials	10 days
17	Pilot plastic	10 days
18	Pilot MCPs	10 days
19	Pilot MFG	5 day
20	**EUA verification inhouse**	**12 days**
21	Specificity 1	5 days
22	LOD	1 day
23	Cross-rxn	2 days
24	Inteferences	5 days
25	Prozone	1 day
26	User guardband	5 days
27	environmental	3 days
28	EUA VER des review1	1 day
29	**EUA pre-clinical action**	**41 days**
30	ID sites	41 days
31	Site contacts	41 days
32	**EUA VER clinicals**	**22 days**
33	Specificity/sensitivity	21 days
34	User	21 days
35	EUA VER des review2	1 day



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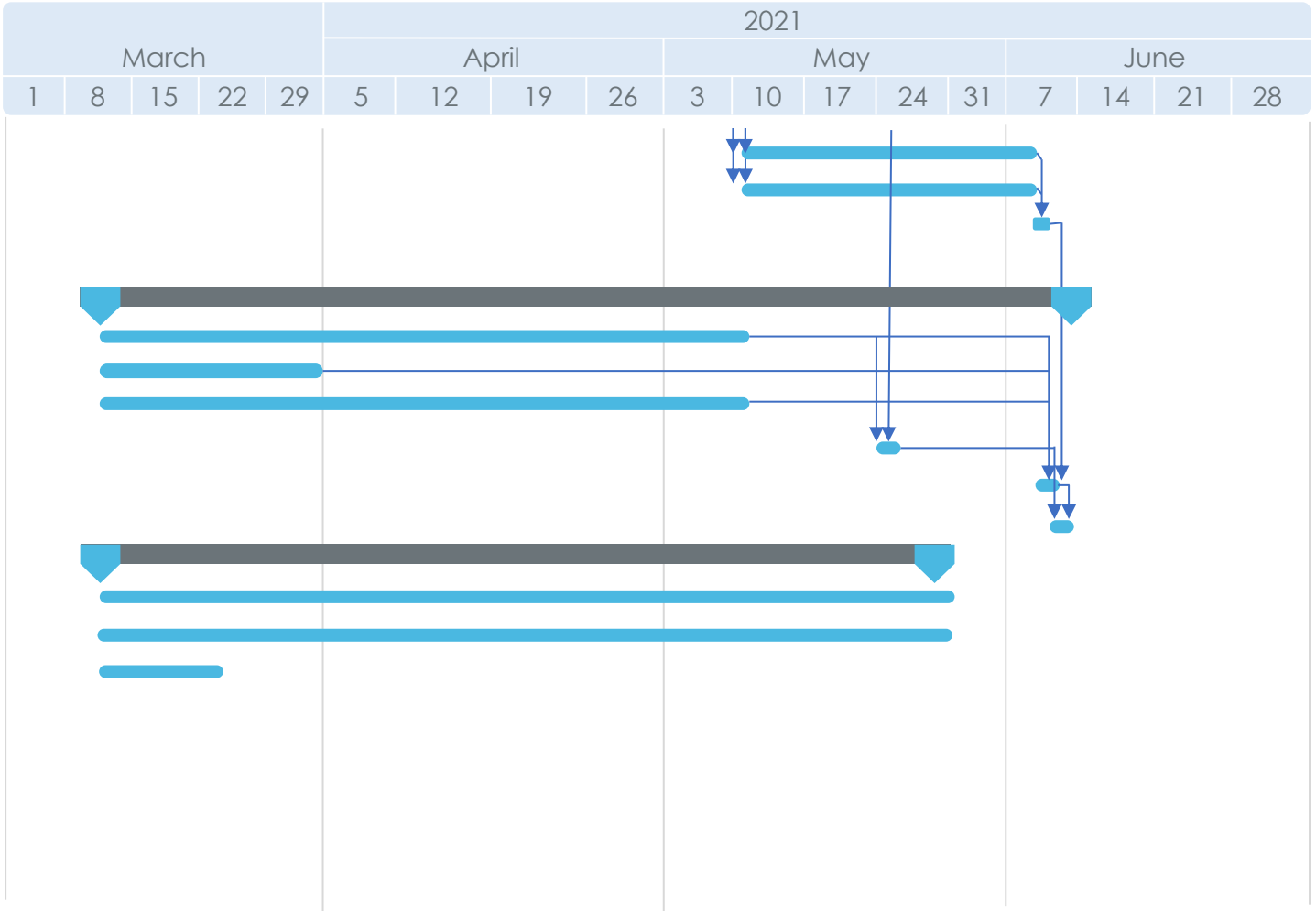
ID	Task Name	Duration
33	Specificity/sensitivity	21 days
34	User	21 days
35	EUA VER des review2	1 day
36	**EUA submission**	**70 days**
37	FDA contact	50 days
38	Final regulatory strategy	20 days
39	Pre-sub info/document	50 days
40	VER inhouse data	1 day
41	VER clinical data	1 day
42	EUA filling	1 day
43	**environmental**	**60 days**
44	37C	60 days
45	Realtime/ambient	60 days
46	Shipping	10 days