



Transforming PCR testing for infectious diseases @ANYWHERE™

Kevin Kraus | CEO

2026 StartupPrize: Health Final Final, FDA Track

August 15, 2026

The Problem

**14M
deaths**

annually from
infectious
diseases

**Lack of
access**

to diagnostic
tests
& treatment

**Unmet
need**

rapid, accurate,
affordable
PCR tests
@ANYWHERE™

Parents lack access to testing in rural areas



What does my child have?

• *Flu* • *RSV* • *COVID-19* • *Strep*

**Need for rapid molecular testing that
reduces unnecessary travel and speeds
treatment decisions**

Sexually active individuals lack access to testing

College campuses & young adults

Do I have an STI?

Chlamydia • Gonorrhea • Syphilis

**Accessible, accurate molecular testing
to diagnosis, treat, and prevent transmission**



Remote & disadvantaged areas lack access to testing



Emerging threats

What could I be exposed to?

Ebola • Malaria • Hantavirus • Avian flu

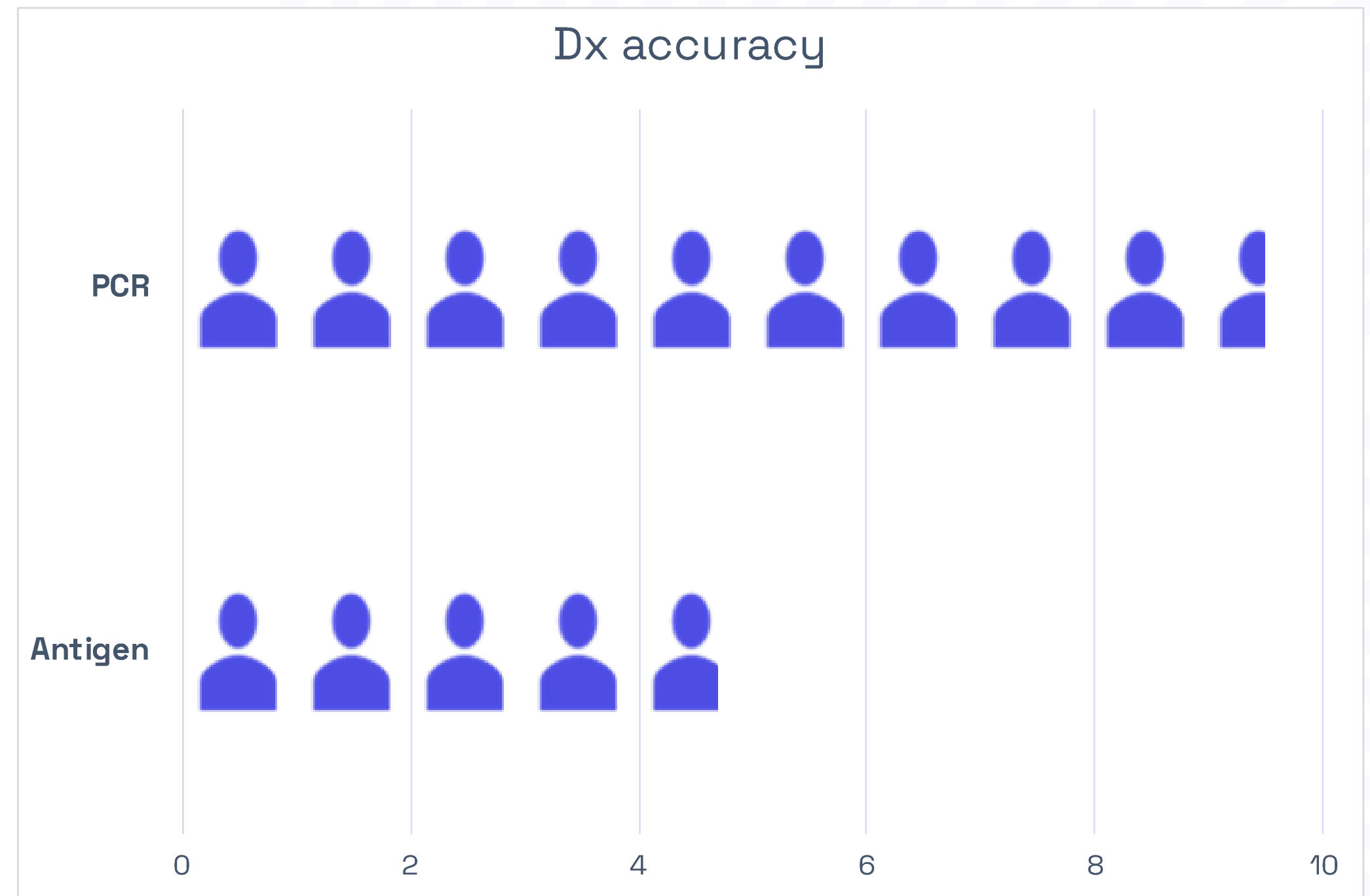


Rapid PCR testing anywhere for economically disadvantaged people and warfighters

Photo: U.S. Army / Marcy Sanchez

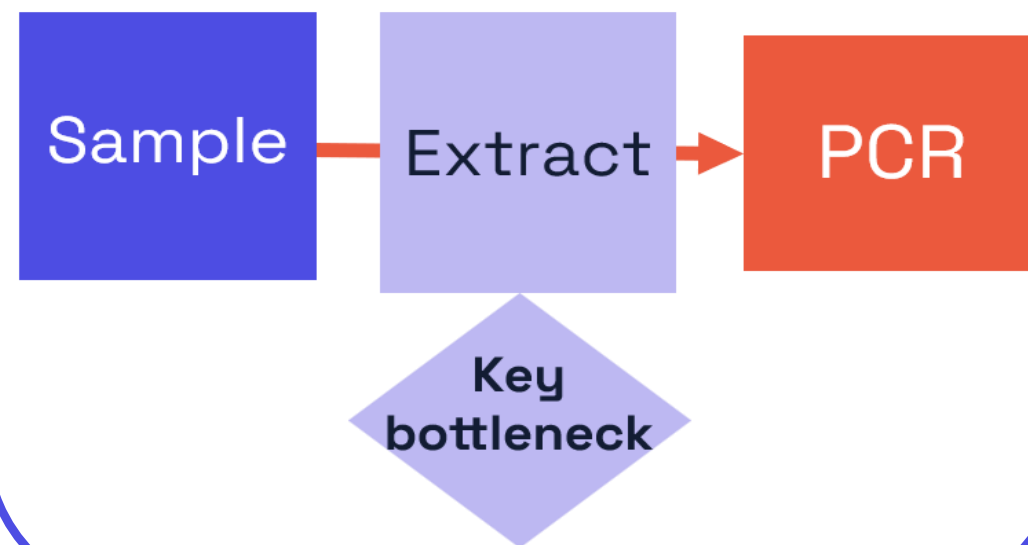
Why gold standard PCR matters?

It is the most accurate for infectious disease diagnostics



Why isn't PCR testing everywhere? It's complex, slow, expensive and stuck in labs

Extraction required



Long time to result & expensive



Skilled staff & expensive equipment



Our platform technologies enable rapid, accurate and affordable PCR testing for infectious diseases



Dramatic improvement vs. conventional PCR

Faster results
(5-14x)

Lower cost
(30%)

Highly accurate

Foundational history

Origins 2019-20

2019 – CU Anschutz advances saliva liquid-biopsy testing for recurrence of head and neck cancer.

2020 – Summit Biolabs (predecessor company) wins CDI Fund development award to further for infectious diseases

 University of Colorado **Anschutz**



Summit Biolabs 2021-22

2021-22 – Summit Biolabs awarded clinical testing contract by CovidCheck Colorado & the State of Colorado.

Result

590,00+ tests performed, \$14M in revenue. GM 80%; EBITDA 50%



Transformative Biotech 2023-26

2023 – Transformative Biotech purchases Summit's IP (post closure) for global deployment

2024 – files patent for lab-on-a-chip @ANYWHERE™ device.

2025-26 - 2 U.S. patents issued for extraction-free pathogen testing (July 2025, July 2026)

Aug. 2026 - CU Anschutz provides formal support. CDI Fund offers conditional investment up to \$100K



Clinically proven direct-to-PCR:
1st in mucosal swabs and to stabilize saliva samples

590,000+

patients tested
for SARS-CoV-2

100%

diagnostic accuracy
(swab)

**Proof of
Concept**

- Flu + COVID
- STIs (CT/NG)

Growing intellectual property estate: 2 issued U.S. patents, 5 pending

Landmark US Patent

12,344,889 Extraction-Free Pathogen Testing



(12) **United States Patent**
Blomquist et al.

(10) **Patent No.:** **US 12,344,889 B2**
(45) **Date of Patent:** ***Jul. 1, 2025**

(54)	EXTRACTION-FREE PATHOGEN TESTING METHODS	FOREIGN PATENT DOCUMENTS
(71)	Applicants: Transformative Biotech, LLC , Boulder, CO (US); The Regents of The University of Colorado , Aurora, CO (US)	EP 3985129 A1 * 4/2022 C12Q 1/6876 WO WO-2013006793 A3 * 5/2013 C12Q 1/68 WO WO-2021133943 A1 * 7/2021 A61M 1/362 WO WO-2021168478 A1 * 8/2021 C12Q 1/6844 WO WO-2021202158 A1 * 10/2021 C12Q 1/6844 WO WO-2022020886 A1 * 2/2022 C12Q 1/6806 WO WO-2022192440 A1 * 9/2022 C12Q 1/6806 WO WO-2022198086 A1 * 9/2022 C12Q 1/701 WO WO-2022236193 A2 * 11/2022 C12Q 1/6806 WO WO-2023287901 A1 * 1/2023 C12Q 1/6806 WO WO-2023081029 A2 * 5/2023 C12Q 1/6806
(72)	Inventors: Robert E. Blomquist , Boulder, CO (US); Shi-Long Lu , Englewood, CO (US); Brian L. Harry , Denver, CO (US); Jose P. Zevallos , St. Louis, MO (US); Xin Yao , Boulder, CO (US)	OTHER PUBLICATIONS
(73)	Assignees: Transformative Biotech, LLC , Boulder, CO (US); The Regents of the University of Colorado , Aurora, CO (US)	Beltran-Pavez et al., 2020. SARS-CoV-2 detection from nasopharyngeal swab samples without RNA extraction. Biorxiv, pp. 2020-03. (Year: 2020).* Blow et al., 2004. Virus inactivation by nucleic acid extraction

Platform extending US patent

12,680,130 Devices and Methods for Extraction-Free Pathogen Testing



(12) **United States Patent**
Blomquist et al.

(10) **Patent No.:** **US 12,680,130 B2**
(45) **Date of Patent:** **Jul. 14, 2026**

(54)	DEVICES AND METHODS FOR EXTRACTION-FREE PATHOGEN TESTING	WO 2021/246820 A1 12/2021 WO 2022/192440 A1 9/2022 WO 2023/081029 A9 10/2024
(71)	Applicants: Transformative Biotech, LLC , Boulder, CO (US); THE REGENTS OF THE UNIVERSITY OF COLORADO , Aurora, CO (US)	OTHER PUBLICATIONS
(72)	Inventors: Robert E. Blomquist , Boulder, CO (US); Shi-Long Lu , Englewood, CO (US); Brian L. Harry , Denver, CO (US); Xin Yao , Boulder, CO (US)	Wei et al. (Jan. 28, 2021, Scientific reports, 11(1), 2402, pp. 1-6).* Lalli et al. (Epub Aug. 6, 2020, MedRxiv, pp. 1-34).* To et al. (2020, The Lancet infectious diseases, 20(5), pp. 565-574).* European Centre for Disease Prevention and Control, 2021, Methods for the detection and identification of SARS-CoV-2 variants, [online], Retrieved [Sep. 26, 2022] Retrieved from the Internet: [https://www.ecdc.europa.eu/sites/default/files/documents/Methods-for-the-detection-and-identification-of-SARS-CoV-2-variants.pdf], 7 pages. FDA, Emergency use Authorization (EUA) Summary Omnigene-Oral OM-505 and OME-505 Saliva Collection Devices, Publication [online] Oct. 28, 2020, Retrieved [Sep. 26, 2022] Retrieved from the Internet: [https://www.fda.gov/media/143419/download#:~:text=
(73)	Assignees: Transformative Biotech, LLC , Boulder, CO (US); The Regents of the University of Colorado , Aurora, CO (US)	

The future of Infectious Disease Diagnostic: Rapid, accurate affordable PCR testing for infectious diseases @ANYWHERE™

NOW



Direct-to-PCR chemistries
& sample collection



Microfluidics
& acoustic mixing

FUTURE

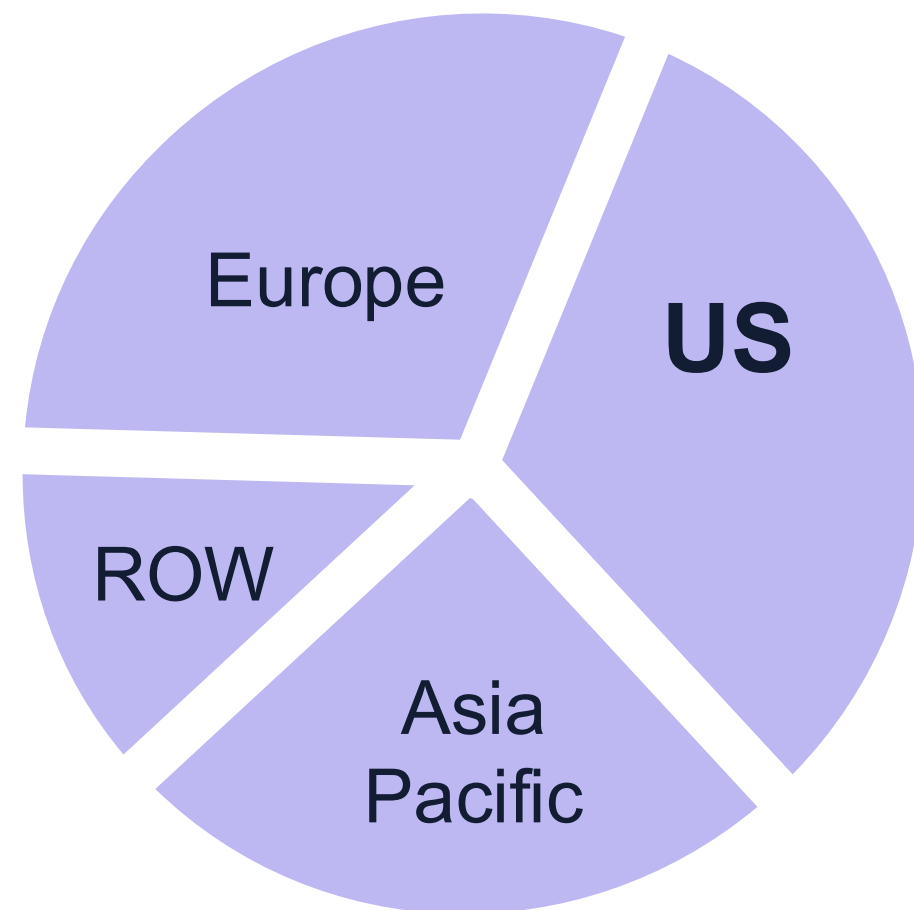


Disposable microfluidic
PCR cartridge



Handheld, smartphone
powered testing device

Target market is \$17 B (2.5B tests) for infectious diseases and growing at 6%



\$5B US Target Market

- 500M tests for infectious diseases (Respiratory, STIs)
- Initial customers:
 - Research use
 - Clinical labs
 - Diagnostic / assay manufacturers

Go-to-market plan

2027

2028

2029

2030

2031

Product Examples

@ANYWHERE™ Sales
Partner licensing, proprietary tests



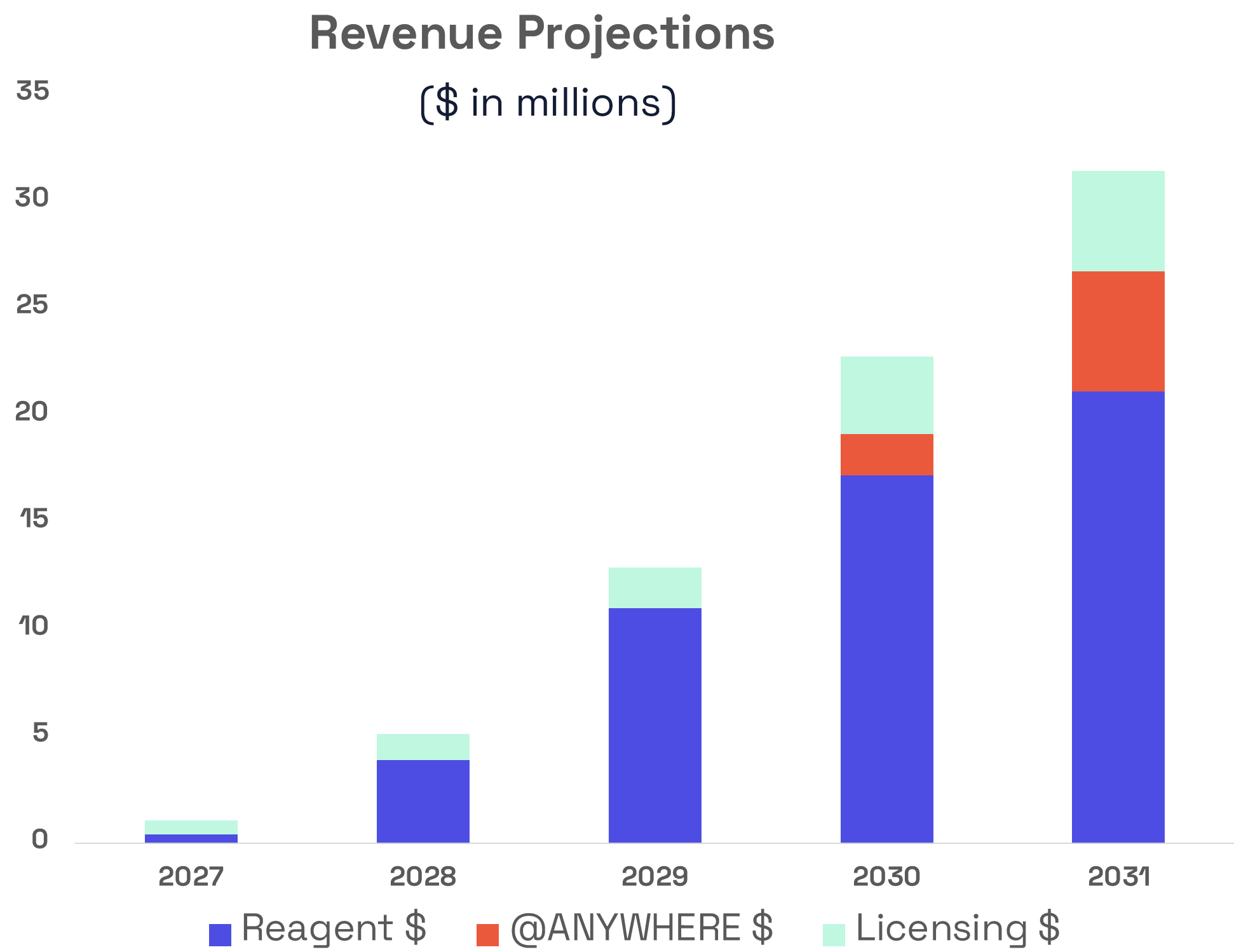
Clinical Lab Sales (IVD) & Licensing
(reagents, sample collection kits via partners, distributors)



Research Use Only (RUO) Sales (DirectAmp™ buffer reagents)



Plan for profitable revenue growth from products and licensing



World class experience in diagnostics, discovery & commercialization



KEVIN KRAUS
CEO



MARK KELLEHER, PHD
EVP, Research & Development



JAY FOUST
EVP, Business Development



SHELLE POURMANAFZADEH ARDABILI
VP, Business Operations



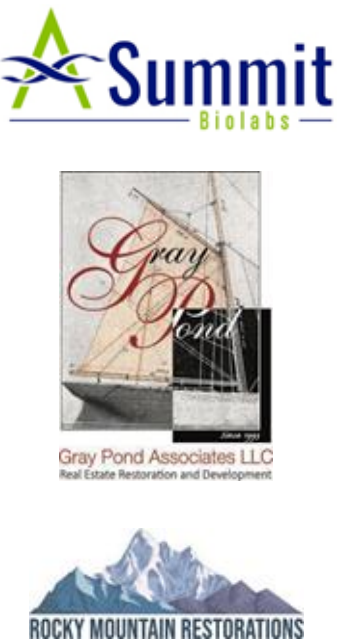
BOB BLOMQUIST
Co-Inventor,
Board Chair



BARBARA HANDELIN, PHD
Board Member



RUSS HULLET
Co-Founder,
Board Member



Science and business advisors: Experts in diagnostics, discovery & development



CHARLES HENRY, PHD
Professor, Chemical & Biological Engineering; Chemistry, Advisor



BRIAN GEISS, PHD
Professor, Microbiology, Immunology & Pathology, Advisor



DAVID DANDY, PHD
Professor, Chemical & Biological Engineering, Advisor



XIAOYUN DING, PHD
Associate Professor, Mechanical Engineering, Co-Inventor @ANYWHERE™



MICKEY URDEA, PHD
Scientific Advisory Board



TONY SHUBER
Scientific Advisory Board



MIREILLE KAMARIZA, PHD
Scientific Advisory Board



LAB / INFECTIOUS DISEASE EXPERT
Pending



Our ask & use of funds

\$2.75M

1st tranche of \$6M raise

Actions

- Broaden data in direct-to-PCR for STIs
- Perform ISO 13485 sample collection kit studies under quality management system
- Develop @ANYWHERE™ proof of concept
- Drive partnership discussions
- Prosecute patents and general operations

Milestones

- STI data package completed
- IVD collection kit for 510(k) process
- @ANYWHERE™ proof of concept
- Revenue from customers & OEMs
- Positioned for growth

Transforming PCR testing for infectious diseases @ANYWHERE™

Team & Advisors

- ✓ Proven in diagnostics, discovery and commercialization



Ask

\$2.75M
1st tranche
of \$6M raise

Clinically proven

- ✓ Direct to PCR: >590,000 clinical tests
- ✓ 10+ strategic partners interested with clear path to monetize & license

Intellectual property estate

- ✓ Two U.S. patents
12,344,889, 12,680,130
- ✓ 5 patents pending

Milestones

- IVD sample collection kit
- Proof of Concept @ANYWHERE
- Customer / OEM sales

Impact

- ✓ Enable @ANYWHERE testing and save lives



We are creating a future where we can identify, treat and stop the spread of disease anywhere





Get in touch!

Kevin Kraus, CEO

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Boulder, CO 80304

transformative-bio.com



Connect on [LinkedIn](#):

Competitive Landscape: PCR testing – moving out of the lab

Lab-based



Point of Care “Luggables”



Direct-to-PCR



1st in raw saliva for SARS CoV-2



Transformative Biotech
(Summit Biolabs)

- 1st in swabs & stabilized saliva (SARS CoV-2)
- 1st in STIs (CT/NG) and Flu
- 1st in non-toxic sample stabilizing solution

@ANYWHERE™



Smartphone powered, handheld device



Transformative Biotech

- 1st to combine proven platform technologies:
- Direct-to-PCR
 - Advanced microfluidics
 - Acoustic mixing

Strategics acquire POC platforms that reduce complexity, time-to-result, or cost

Company	Lex Dx	Curiosity	Iquum	Mesa	BioFire	Alere
Revenue	Early Revenue	Pre-Revenue	~\$25M (LIAT)	\$45M	~\$70M	\$2.5B
Multiple	High	High	>10x	>10x	6 - 7x	2 - 3x*
Exit Value	~\$100M	\$130M	\$450M**	\$550M**	\$485M	\$5.3B
Acquiror						
Year	2026	2022	2014	2021	2014	2017

* Equity Value / Revenue multiple; ** = including milestone payments

Traction: Under discussion with strategic partners

Engaged

Device

Lab

Others



Non-dilutive funding strategy: Current opportunities (\$500k) & next milestones, with other groups engaged

Program	Next Milestone	Submission Date	Potential 2026- 2027 Funding (if awarded)
OEDIT Early Stage Capital and Retention Grant	Submit application	Sept. 2026	\$250K
NIH SBIR/STTR	Submit Phase I proposal with CSU	Sept. 2026	\$125K
Swine Flu Grant	Build full proposal based on review	Dec. 2026	<u>\$125K</u>

\$500k

Total current non-dilutive funding opportunity

Engaged



Intellectual property details

Product / Family	Relevant IP	Status	What it supports	Rights / Strategic role
DirectAmp™ chemistry	SBIO-002 / US 12,344,889	ISSUED	Extraction-free chemistry + workflow	Foundational protection
Sample collection / DirectAmp™	SBIO-004 / US 12,680,130 + SBIO-001	ISSUED + PENDING	Swab/saliva and additional sample workflows	Expands sample applications
STI testing	SBIO-005	PENDING	Extraction-free STI workflows	Expands disease applications
@ANYWHERE™	SBIO-006	PENDING	Acoustic microfluidics / portable PCR	Device/platform protection
Future molecular platform	SBIO-007	PENDING	Hybrid nucleic-acid analysis using microfluidics	Potential expansion beyond conventional PCR

Intellectual property details (continued)

Status	Name	Note:
1 issued U.S. patent	US Patent 12,344,889 Extraction-Free Pathogen Testing	Issued by USPTO on July 1, 2025. Covers core chemistry and workflow (composition of matter and method). Exclusive global license agreement and FTO from co-inventor, CU Anschutz.
2nd issued U.S. patent	US Patent 12,680,130 Devices and Methods for Extraction-Free Pathogen Testing	Issued by USPTO on July 14, 2026. Expands coverage to additional sample matrices, including swab and saliva.
U.S. patent application pending	US 17/244,333 – Saliva Viral Testing	Pending application to expand matrix coverage.
U.S. patent application pending	US 18/559,120 – Variant Detection (PCR)	Reinforces the chemistry across SARS-CoV-2 variant detection workflows.
U.S. patent application pending	US 17/972,111 – Extraction-Free STI Testing (PCR)	Bacterial detection with STI swabs. Supports self-collection and at-home diagnostics.
U.S. patent application pending	US 19/016,825 – Acoustic Microfluidics PCR Device	Pending application directed to acoustic microfluidic PCR device innovations @ANYWHERE™ device-level innovation. Co-option license agreement from University of Colorado Boulder (through Feb 1, 2027)
U.S. patent application pending	US (# pending) SYSTEM AND METHOD FOR EXTRACTION-FREE HYBRID NUCLEIC ACID ANALYSIS	Pending application directed to microfluidic PCR device innovations @ANYWHERE™ device-level innovation with Colorado State University. License and IP to be determined after non-dilutive or dilutive funding.

Additional jurisdictions include Europe, Canada and Japan, further information available upon request under NDA.

Diagnostic test accuracy: sensitivity & specificity

- Sensitivity measures how often a test correctly generates a ***positive*** result for people who ***have*** the condition that's being tested for
- Specificity measures a test's ability to correctly generate a ***negative*** result for people who ***don't*** have the condition that's being tested for
- The terms Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) should be used in place of Sensitivity and Specificity, respectively, when the comparator is known to contain uncertainty

Diagnostic Test Accuracy Measure	Yale SalivaDirect (as an example)	Implications
Sensitivity/PPA, %	94.1%	~6 people out of 100 tested would receive a <i>false negative result</i> , but who have COVID-19
Specificity/NPA, %	90.9%	~9 subjects out of 100 tested would receive a <i>false positive result</i> , but who don't have COVID-19

[HealthNewsReview](#), accessed 2020-12-2, [Mallett, et al 2012](#), [McHugh, et al. 2019](#), Yale SalivaDirect EUA 202097 dated 2020-8-15

Clinical validation: our direct-to-PCR proven equivalent to conventional PCR

Summit Biolabs tests	DISEASE	SAMPLE TYPE	POSITIVE PERCENT AGREEMENT	NEGATIVE PERCENT AGREEMENT
CLINICAL STUDY				
COVIDFast	COVID-19	swab	100%	100%
COVIDFast	COVID-19	saliva	98.8%	99.4%
PROOF OF CONCEPT STUDY				
FLUVIDFast	COVID-19	swab	92.9%	99.2%
	COVID-19	saliva	92.0%	99.6%
	Flu	swab or saliva	100%	—

Clinical evidence: COVIDFast dtPCR swab is substantially equivalent to extraction PCR for SARS-CoV-2 detection

		CDC Protocol Swab RNA Extraction*		
		+	-	
COVIDFast™ Swab dtPCR*	+	38	0	38
	-	0	31	31
		38	31	69
PPA = 100 %				
NPA = 100 %				

* Both tests employ modified CDC Protocol with multiplex assay and positive cutoff 36
Summit Biolabs' FDA EUA submission, dated 2022-1-14
Conducted under approved IRB

Our direct-to-PCR shows equivalent PCR performance

Published* benchmarking vs. extraction-based PCR

What we tested

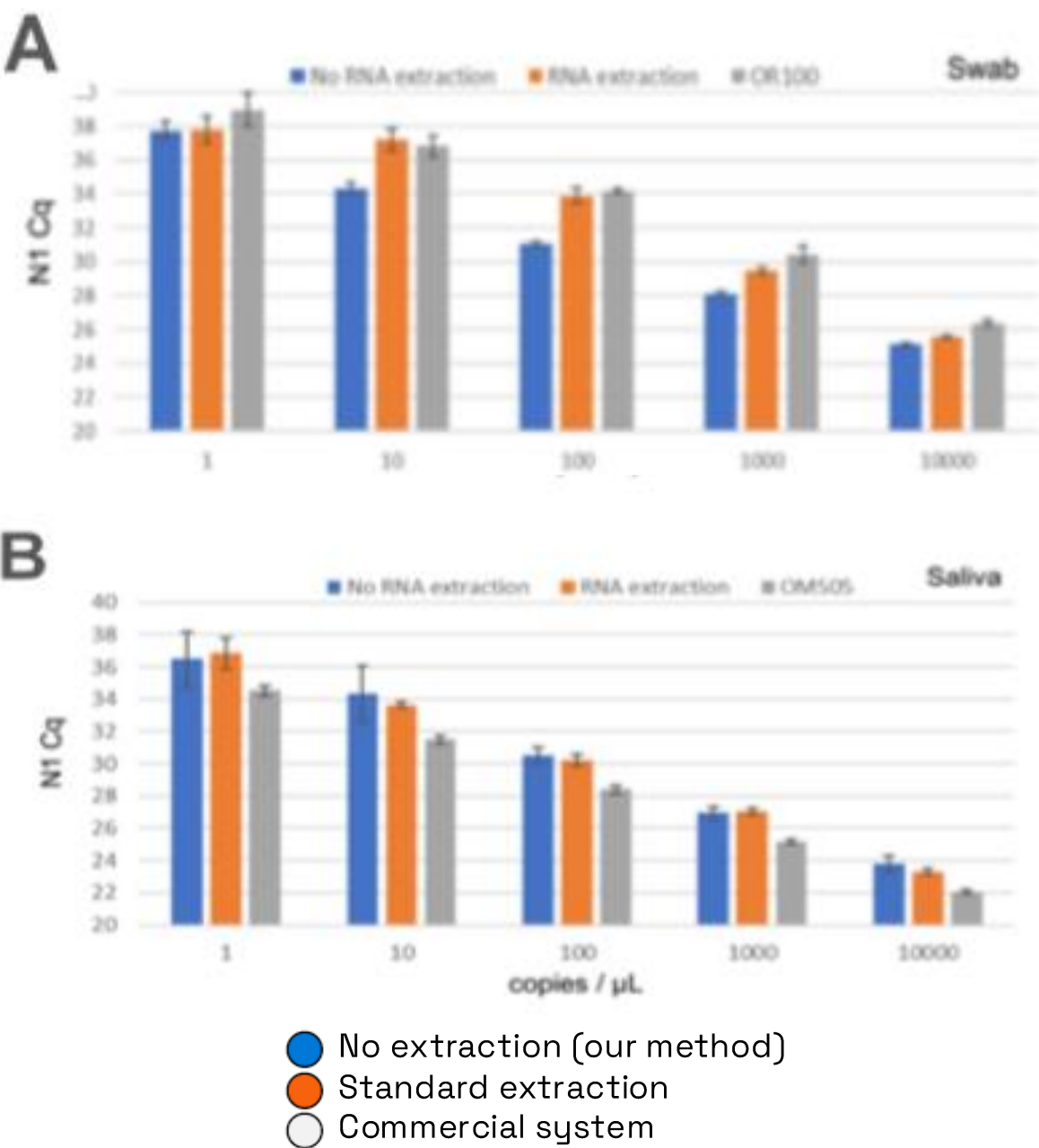
- SARS-CoV-2 in swab and saliva across viral loads

What we compared

- DirectAmp™ (no extraction) vs. standard extraction vs. commercial system

What we found

- Equivalent Ct values across sample types and viral loads
- Maintained sensitivity (LoD) at low copy levels
- Consistent, reproducible performance



Showing copies/ μ L (x-axis) of heat inactivated SARS-CoV-2 spiked into samples collected in cryovials or commercial collection device. Cryovials were extracted (orange) and not extracted (blue) commercial device was extracted grey) Panel A swabs, Panel B saliva. (from Qiu et al J biotechnol biomed 2024)

* Qiu Y, et al. *Journal of Biotechnology & Biomedicine*. 2024.

Ct (cycle threshold): number of cycles needed to detect the virus, lower = more virus. LoD (limit of detection): the lowest amount of virus the test can detect.

Ebola: A Case for Rapid, Adaptable Molecular Testing

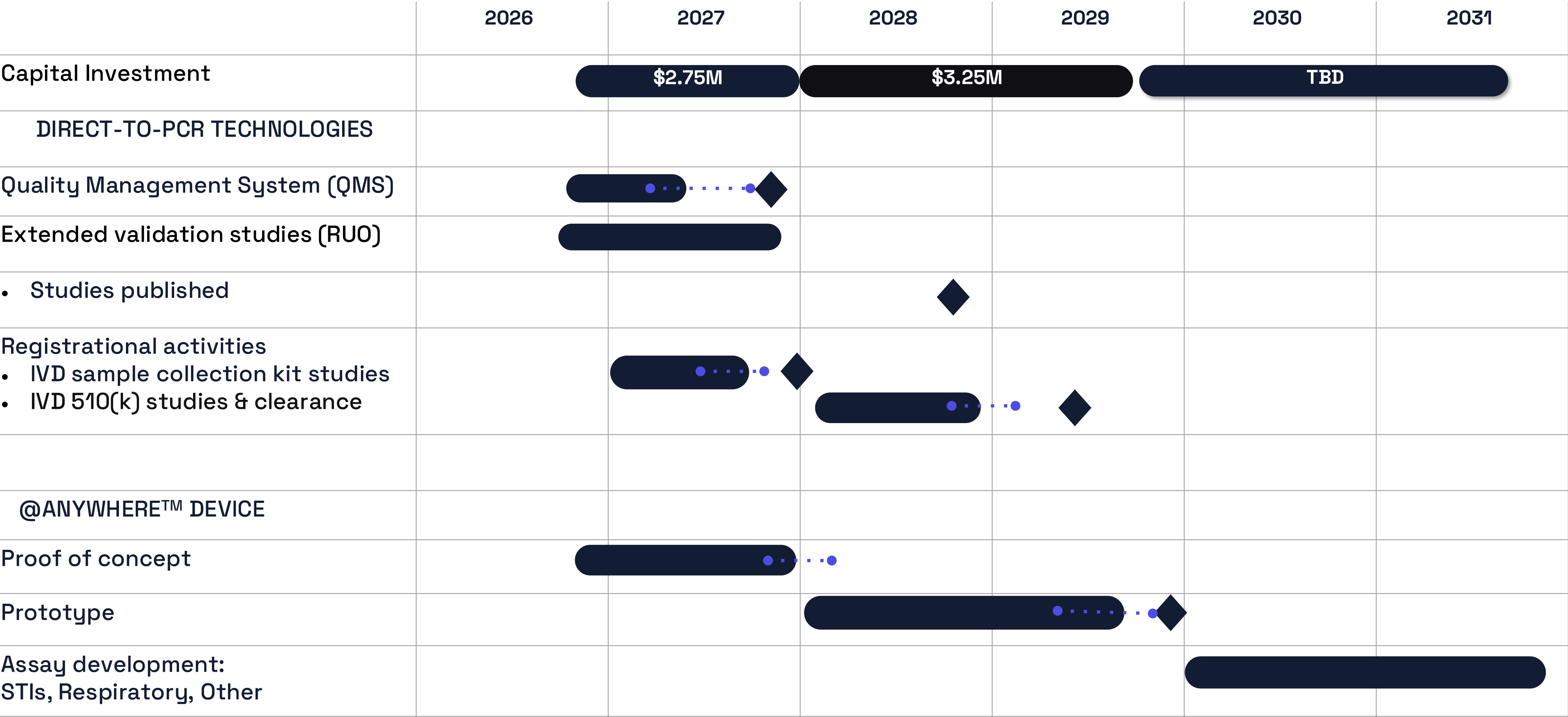
Ebola is a viral hemorrhagic fever caused by orthoebolaviruses; RT-PCR remains a key method for laboratory confirmation.

Recent DRC outbreak illustrates the diagnostic challenge: Bundibugyo virus circulated before the outbreak was recognized, with early illness difficult to distinguish from diseases such as malaria and typhoid; WHO subsequently emergency-listed the first molecular diagnostic specifically for Bundibugyo in July 2026.

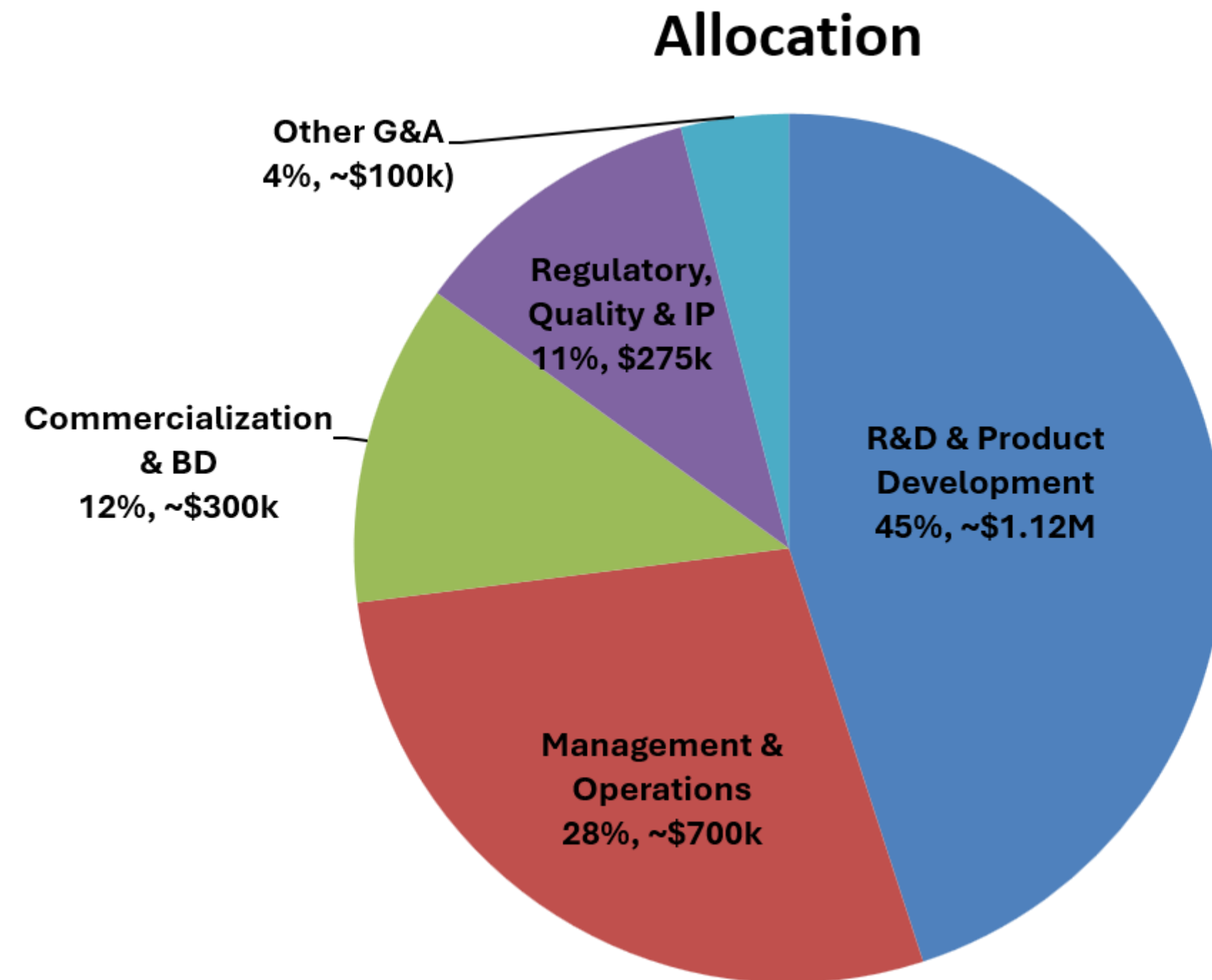
Point-of-need testing is already established: OraSure's OraQuick™ Ebola 2.0 rapid antigen test detects four disease-causing orthoebolaviruses and can test whole blood in living patients or oral fluid from recently deceased individuals, helping protect healthcare and burial workers.

Transformative Biotech opportunity: DirectAmp™ has **not yet been clinically evaluated for Ebola**, but we believe its extraction-free approach warrants evaluation with qualified partners as a way to potentially simplify PCR workflows and reduce sample-preparation steps.

Use of funds

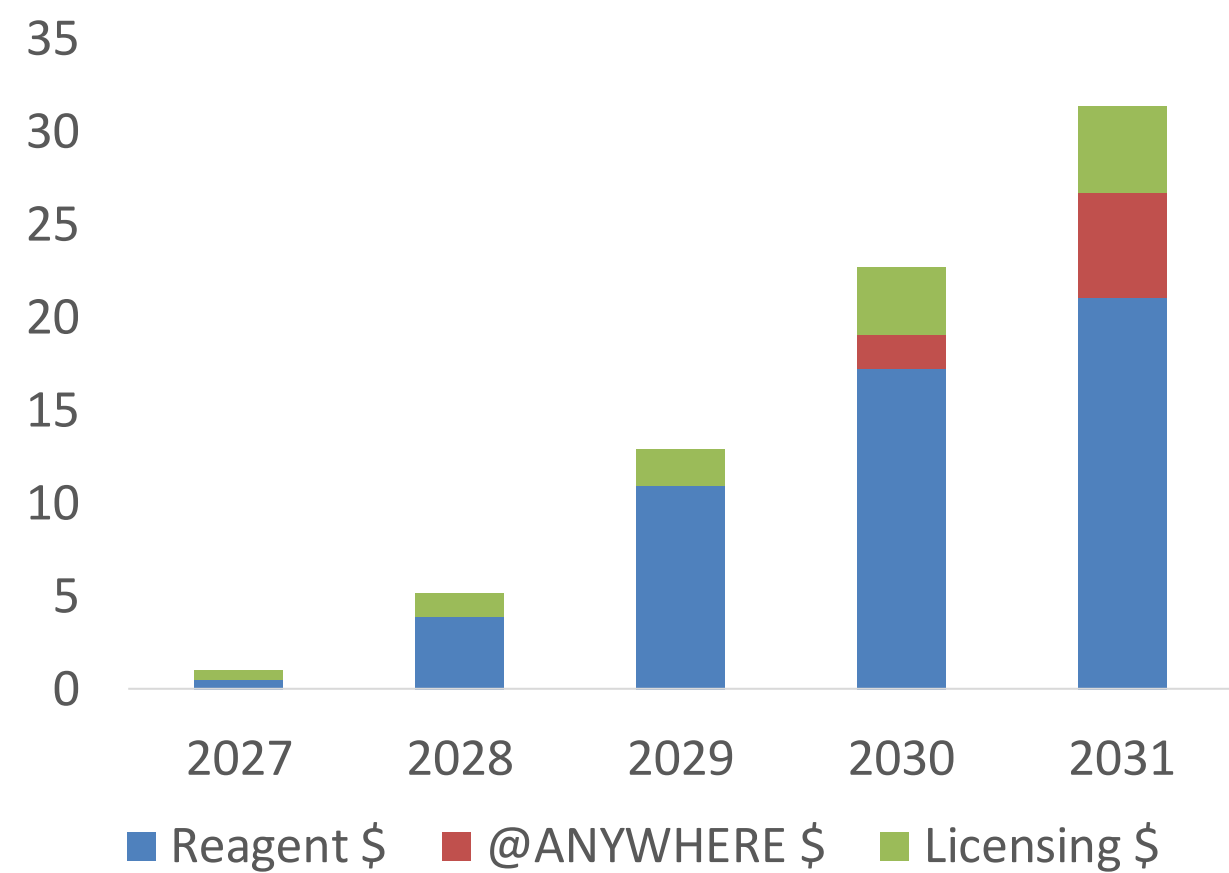


\$2.75M supports a staged 2027 operating plan



Revenue plan supported by bottom-up DirectAmp™ assumptions

Revenue Projections



Revenue type	2027	2028	2029	2030	2031
Reagent \$	0.5	4	11	17	21
@ANYWHERE \$	0.0	0	0	2	6
Licensing \$	0.6	1	2	4	5
Sum	1.1	5	13	23	31

DirectAmp revenue assumptions

RUO price / test	\$8
IVD price / test	\$10
RUO trial order	~200 tests
RUO recurring order	~1K tests
IVD recurring order	~10K tests

~80% Target gross margin

Illustrative licensing model

	Non-exclusive	Preferred / Co-exclusive	Field exclusive
Upfront fee	\$25K	\$60K	\$350K
Milestone payments	\$35K	\$110K	\$1.5M
Royalty	2%	4%	6%
Illustrative max net sales	\$0.5M	\$2.5M	\$25M

Potential fields of use: Infectious Disease • Oncology • Veterinary • Agriculture/Food Safety • Forensics
Potential platforms: PCR • NGS • Other molecular workflows

*Subject to technical validation, IP scope and applicable license rights.

\$500K initial financing launches our \$2.75M first tranche

Accelerates customer validation, sales and IP milestones

CU Anschutz Letter of Support, August 11, 2026



Innovations
UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

CU Anschutz Innovations

Campus Stop F411
1890 N. Revere Ct., Suite 6202 | Aurora, CO 80045
o 303-724-3720 | f 303-724-0816 | cuinnovations@cuan
http://cuanschutz.edu/cu-innovations

August 11, 2026

Dear Kevin Kraus,

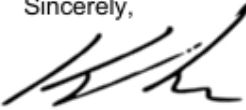
CU Innovations, the technology transfer office for the University of Colorado Anschutz (CU Anschutz), is pleased to provide a letter of support for Transformative Biotech. CU Anschutz Innovations brings together industry partners, entrepreneurs, and investors to help researchers create biomedical technology that improves the quality of life worldwide. With expertise in patents, copyrights, trademarks and licensing, CU Innovations translates discovery into impact through transparent, flexible, best practice intellectual property management. We connect researchers at the CU Anschutz Medical Campus with a variety of commercialization programs in the University and the community. Our organization is a leader in technology development, ranked in the top 20 of universities globally for patent activity, and recently recognized by Nature as the 4th top academic institution globally for forging strong innovation links.

Our flagship accelerator program, SPARK Colorado, aims to support translational projects that will improve human health. It is built on three pillars: funding for two years; industry mentorship on product development and commercialization; and overall training on translating academic discoveries to the market to solve pressing health challenges. We are proud to have supported the underlying technology at Transformative Biotech in Cohorts 1 of the SPARK program to advance its development towards a commercial launch and positive patient impact.

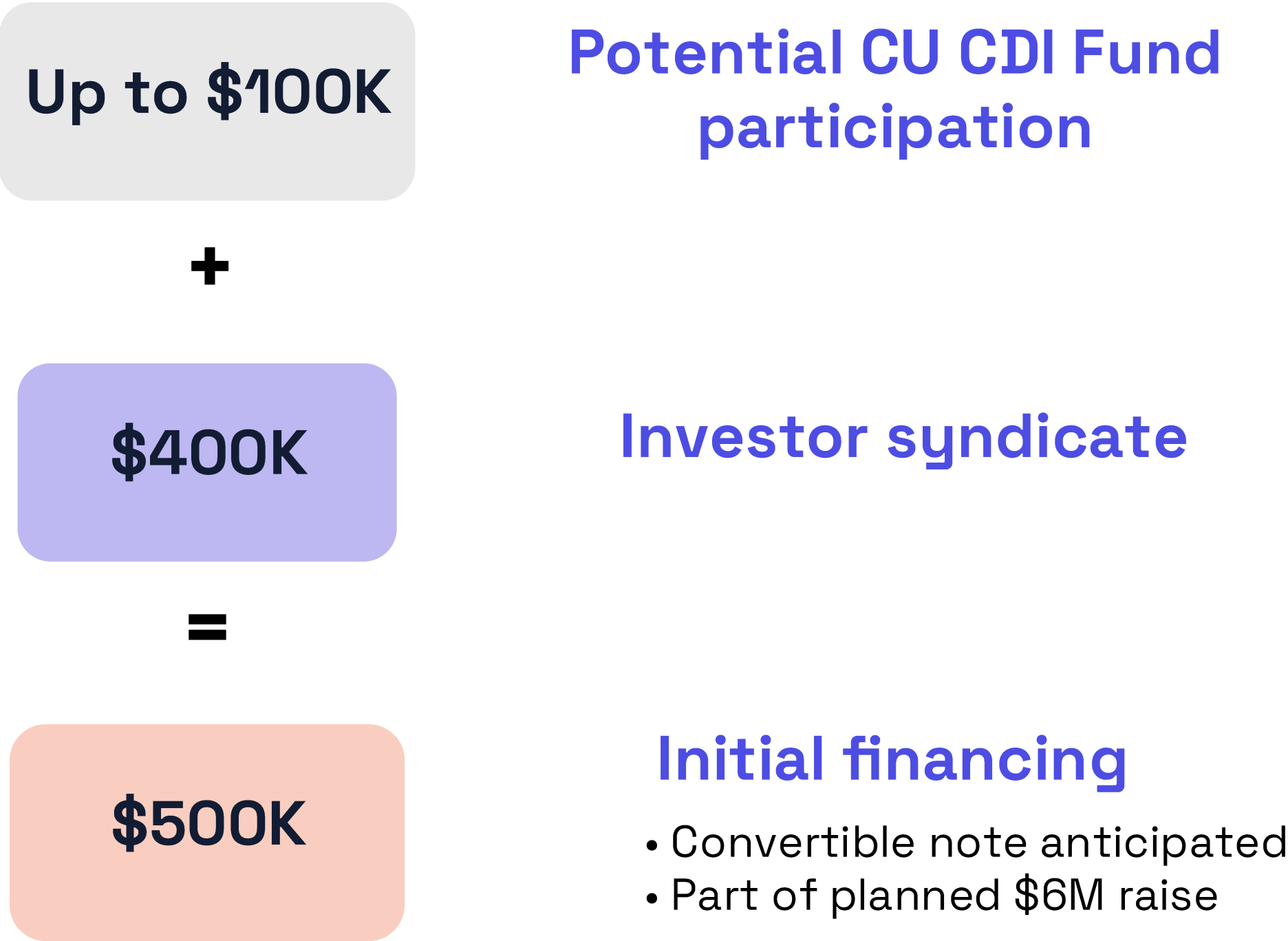
CU Innovations also manages the \$5M Chancellor's Discovery and Innovation Fund (CDI Fund) and the CU Healthcare Innovation Fund (CUHIF), a venture capital fund with \$100M+ in assets under management to invest in promising CU Anschutz startup companies and partners. Should a strong investor syndicate coalesce around Transformative Biotech, the CDI Fund could participate in the financing with up to \$100K as a convertible debt note investment. In my role as Partner at the CUHIF, I confirm that we will also evaluate an investment should a strong investor syndicate coalesce around the company in subsequent investment financings post the seed financing.

Our office recognizes that this high-value emerging technology would fill an important unmet clinical need that would greatly enhance the efficiency of diagnostic testing with direct-to-PCR extraction-free modalities. As a graduate of the SPARK Colorado program and custodian of CU Anschutz IP, we are delighted to offer our most enthusiastic support.

Sincerely,



Gali Baler, PhD, MBA
Managing Director of Ventures and Investment, CU Anschutz Innovations
Partner, CU Healthcare Innovation Fund
University of Colorado Anschutz



\$500K advances key validation & commercialization milestones

Product Validation

- 2 - 3 customer evaluations
- STI data package

Commercialization

- DirectAmp™ & collection kit
- Partner evaluations, licensing + initial sales

IP + Financing

- Key patent families
- Position for \$2.75M first tranche



\$100M+ AUM • Potential follow-on investment with strong investor syndicate

Use of funds from CU Innovations’ support and initial financing syndicate that will unlock the next stage of growth

Expected Outcomes: Complete key technical, commercial, and IP milestones to support **\$2.75M institutional financing in 2027.**

Allocation	Investment Priority	Key Milestone
\$250K	DirectAmp™ product evaluation studies	2 - 3 customer evaluations completed, STI data package extended
\$100K	Patent prosecution & portfolio expansion	Advance two patent families (direct-to-PCR and @ANYWHERE)
\$50K	Data generation & technical validation	Generate partner and grant-supporting datasets
\$75K	Operations & commercialization	Secure lead investor and 2 - 3 co-investors / partners
<u>\$25K</u>	Partnerships and legal support	Advance licensing and commercial readiness

**\$500k
Total**