Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation: the impact and duration of the novel virus (COVID-19) global pandemic; funding and compliance risks relating to government contracts, including the ability to meet key deliverables and milestones under our NIH RADx-ATP contract; our ability to accurately forecast demand for our products and products in development, including in new market segments; adverse changes in competitive conditions, the reimbursement system currently in place and future changes to that system, changes in economic conditions in our domestic and international markets, lower than anticipated market penetration of our products, our reliance on sales of our influenza and COVID-19 diagnostic tests, fluctuations in our operating results resulting from the timing of the onset, length and severity of cold and flu seasons, seasonality, government and media attention focused on influenza and other respiratory or novel viruses and the related potential impact on humans from such viruses, the quantity of our product in our distributors’ inventory or distribution channels, changes in the buying patterns of our distributors, and changes in the healthcare market and consolidation of our customer base; our development, acquisition and protection of technology rights; our ability to develop new technologies, products and markets and to commercialize new products; our reliance on a limited number of key distributors; our exposure to claims and litigation that could result in significant expenses and could ultimately result in an unfavorable outcome for us, including the ongoing litigation between us and Beckman Coulter, Inc.; intellectual property risks, including but not limited to, infringement litigation; our ability to finance our capital or operating needs; the financial soundness of our customers and suppliers; acceptance of our products among physicians and other healthcare providers; competition from other providers of diagnostic products; failures or delays in receipt of new product reviews or related to currently-marketed products by the U.S. Food and Drug Administration (the “FDA”) or other regulatory authorities or loss of any previously received regulatory approvals or clearances or other adverse actions by regulatory authorities; changes in government policies; costs of and adverse operational impact from failure to comply with government regulations in addition to FDA regulations; compliance with government regulations relating to the handling, storage and disposal of hazardous substances; third-party reimbursement policies and potential cost constraints; our failure to comply with laws and regulations relating to billing and payment for healthcare services; our ability to meet demand for our products; interruptions or shortages in our supply of raw materials and other components; product defects; business risks not covered by insurance; costs and disruptions from failures in our information technology and storage systems; our exposure to data corruption, cyber-based attacks, security breaches and privacy violations; competition for and loss of management and key personnel; international risks, including but not limited to, compliance with product registration requirements, compliance with legal requirements, tariffs, exposure to currency exchange fluctuations and foreign currency exchange risk, longer payment cycles, lower selling prices and greater difficulty in collecting accounts receivable, reduced protection of intellectual property rights, social, political and economic instability, increased financial accounting and reporting burdens and complexities, taxes, and diversion of lower priced international products into U.S. markets; changes in tax rates and exposure to additional tax liabilities or assessments; our ability to identify and successfully acquire and integrate potential acquisition targets; our ability to manage our strategies and identify and integrate acquired companies or technologies and our ability to obtain financing; the level of our deferred payment obligations; that our Revolving Credit Facility is secured by substantially all of our assets; the agreements for our indebtedness place operating and financial restrictions on us and our ability to operate our business; that an event of default could trigger acceleration of our outstanding indebtedness, that we may incur additional indebtedness; dilution resulting from future sales of our equity; volatility in our stock price; provisions in our charter documents and Delaware law that may delay or impede stockholder actions with respect to business combinations or similar transactions; and our intention of not paying dividends. Forward-looking statements typically are identified by the use of terms such as “may,” “will,” “should,” “might,” “expect,” “anticipate,” “estimate,” “plan,” “intend,” “goal,” “project,” “strategy,” “future,” and similar words, although some forward-looking statements are expressed differently.

Forward-looking statements in this presentation include, among others, statements concerning: our outlook for the business, including, among others, projections about our revenue, revenue profile, gross margins, free cash flow, indebtedness, capital expenditures, development, expenses, including research and development (“R&D”) and sales and marketing (“S&M”), EBITDA, market opportunities, geographic expansion, and development, manufacturing, regulatory and commercial activities; our strategic initiatives, goals and objectives; our merger and acquisition (“M&A”) strategy. The risks described in reports and registration statements that we file with the Securities and Exchange Commission (the “SEC”) from time to time, should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management’s analysis only as of the date of this presentation. Except as required by law, we undertake no obligation to publicly release any revision or update of these forward-looking statements, whether as a result of new information, future events or otherwise.

- **Projections:** The projections and estimates used in this presentation are based on numerous variables and assumptions, which are inherently uncertain, including factors related to the impact of the COVID-19 pandemic, continuity of supply of raw materials and other components, general economic and competitive conditions. Accordingly, actual results could differ materially from those set forth in the projected or estimated numbers. Inclusion of such projected and estimated numbers in this presentation should not be regarded as a representation that such results will be achieved. See “Forward-Looking Statements” above.

- **Non-GAAP Financial Measures:** This presentation contains adjusted EBITDA, which is a non-GAAP financial measure. Such non-GAAP financial measures are presented as supplemental financial measurements in the evaluation of our business. We believe the presentation of these financial measures helps investors to assess our operating performance from period to period and enhances understanding of our financial performance and highlights operational trends. Such measurements may not be comparable to those of other companies in our industry, which limits their usefulness as comparative metrics. Such metrics are not required by or calculated in accordance with generally accepted accounting principles (“GAAP”) and should not be considered as substitutes for net income or any other measure of financial performance reported in accordance with GAAP or as a measure of operating cash flow or liquidity. You can find a description and other important information regarding adjusted EBITDA in the financial section of this presentation, and a reconciliation of the most directly comparable GAAP financial measure.
<table>
<thead>
<tr>
<th>Topic</th>
<th>Presenter</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction and Overall Strategy</td>
<td>Doug Bryant</td>
<td>10 mins</td>
</tr>
<tr>
<td>Growth Drivers (pre-COVID)</td>
<td>Savanna</td>
<td>30 mins</td>
</tr>
<tr>
<td></td>
<td>hs-Troponin</td>
<td></td>
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<td></td>
<td>Sofia</td>
<td></td>
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<tr>
<td></td>
<td>Johannes Kehle and Tammi Ranalli</td>
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<td></td>
<td>Bill Ferenczy</td>
<td></td>
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<tr>
<td></td>
<td>Rhys de Callier</td>
<td></td>
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<tr>
<td>Growth Drivers (current state)</td>
<td>Doug Bryant</td>
<td>5 mins</td>
</tr>
<tr>
<td></td>
<td>COVID-19 product pipeline</td>
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<tr>
<td>Big Ideas</td>
<td>Karen Gibson</td>
<td>20 mins</td>
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<td>Project “Sniffles”</td>
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<td></td>
<td>Werner Kroll</td>
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<td></td>
<td>Project “Leapfrog”</td>
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<tr>
<td>M&amp;A and Financial Update</td>
<td>Randy Steward</td>
<td>20 mins</td>
</tr>
<tr>
<td>Live Q&amp;A Session</td>
<td>Doug Bryant, Randy Steward</td>
<td>60 mins</td>
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# Savanna key development factors & differentiators

<table>
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<tr>
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<tbody>
<tr>
<td>• Magnetic bead based nucleic acid isolation</td>
<td>• Fast data readout by unique light fiber optics</td>
<td>• Direct swab and liquid sample compatibility</td>
<td>• Main bay drives up to 3 auxiliary bays</td>
</tr>
<tr>
<td>• 4 color PCR multiplexing for up to 12 analytes/run</td>
<td>• qPCR with 45 cycles in &lt; 12min</td>
<td>• Reagents stable at room temperature</td>
<td>• Auxiliary bays added vertically or horizontally</td>
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</table>

<table>
<thead>
<tr>
<th>5. Assay versatility</th>
<th>6. Assay development strategy</th>
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<tbody>
<tr>
<td>• Qualitative/quantitative assays compatible</td>
<td>• Develop critical mass of assays near launch time</td>
</tr>
<tr>
<td>• Combined pathogen/AST testing in one assay run</td>
<td>• Scalable assay manufacturing concept</td>
</tr>
</tbody>
</table>
Savanna’s disposable cartridge

Robust technologies

PCR chambers
Four independent chambers for up to 12 analytes per run through very fast qPCR

Simplicity and ease-of-use

Swab sample port
Direct swab addition

Liquid sample port
Accommodating sample volumes from 50µl to 200µl (overflow chamber for simple liquid sample addition and correct volume introduction into cartridge)
Small Footprint
Intuitive touch screen
Illuminated cartridge bay
Integrated bar code reader
Full, built-in connectivity
Up to 3 auxiliary bays
Savanna® offers true sample-in, result-out operation.

Results in <20mins (RVP10 Panel)
Savanna® Timeline

12/2020
Clinical trial instruments available

1/2021
Clinical trial start (1st assay)

4/2021
Final instrument prototype version ready

6/2021
Commercial launch (1st assay)

10/2021
Commercial launch (additional panels)

510(k) Clinical trials for panels 2-5
Savanna

Tammi Ranalli, PhD
SVP, Molecular Dx
Covid has had a large impact on the global market with PCR and Immunoassay modalities absorbing this new volume

## Global respiratory diagnostics testing volume

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>2024</th>
<th>CAGR</th>
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<tbody>
<tr>
<td>Micro</td>
<td>509.6</td>
<td>493.8</td>
<td>489.8</td>
<td>485.8</td>
<td>481.9</td>
<td>477.9</td>
<td>-1.3%</td>
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<tr>
<td>PCR</td>
<td>1,281.3</td>
<td>3,986.0</td>
<td>3,040.0</td>
<td>2,641.0</td>
<td>2,750.0</td>
<td>2,891.0</td>
<td>17.7%</td>
</tr>
<tr>
<td>NGS</td>
<td>174.7</td>
<td>385.0</td>
<td>403.0</td>
<td>285.0</td>
<td>303.0</td>
<td>318.6</td>
<td>12.8%</td>
</tr>
<tr>
<td>IA</td>
<td>1,528.8</td>
<td>2,697.0</td>
<td>2,764.0</td>
<td>2,286.0</td>
<td>2,150.0</td>
<td>2,065.0</td>
<td>6.2%</td>
</tr>
<tr>
<td>Other</td>
<td>145.6</td>
<td>146.6</td>
<td>146.8</td>
<td>147.0</td>
<td>147.3</td>
<td>147.5</td>
<td>0.3%</td>
</tr>
<tr>
<td>Total</td>
<td>3,640.0</td>
<td>7,708.3</td>
<td>6,843.6</td>
<td>5,844.9</td>
<td>5,832.1</td>
<td>5,900.0</td>
<td>10.1%</td>
</tr>
</tbody>
</table>

- United States: CAGR ~18%
- EMEA: CAGR ~16%
- APAC: CAGR ~18%
- ROW: CAGR ~15%

Source: Biopharma-research
Current competitive platforms

**Cepheid**

TAT: 30’-50’
Menu: Broad
Panels: Up to 4 analytes, no test select
Cost: Moderate
Performance: Excellent
Base: 11,000 Cepheid placements

**BioFire**

TAT: 45’
Menu: GI/Resp/Meningitis
Panels: Large, inflexible
Cost: Expensive >$100 panels
Base: 10,400 BioFire placements

Savanna® platform

**Fast**

High performance

**Flexible panels**

Scalable

**Broad test menu**

Cost effective
Provide differentiating therapeutically actionable clinical results

Provide CLIA waived solution that solve the needs in simplicity, hands-on time, turn around time

Address limitations of single parameters as delivered by current systems

Addresses and implements move from fee for service medicine to value-based diagnostics

Address reimbursement issues created by large array panels or NGS based assays

Savanna Menu

Develop critical mass of target sized mini panels (4 to 12 analytes)
Savanna Launch Strategy

EUA
Address immediate need with EUA of respiratory panel in 2021 prior to 510k clearance

Partner
Partner with leading institutions to quickly demonstrate utility and clinical performance: Northwell, UPMC, Georgetown, Yale, Barnes Jewish, Mercy Health, NY Presbyterian, Baylor, Scott & White

Capitalize
Capitalize on relationships accelerated through launch of Covid molecular products
  • Lyra Covid customers
  • Solana customers

Solidify & Expand
Solidify and Expand customer base with additional relevant menu
Looking Beyond Covid-19: Savanna Menu

- **Sexually Transmitted Disease**
  - Herpes/Syphilis Panel
  - Vaginitis Panel
  - STI Panel/STI resistance Panel

- **Gastrointestinal Disease**
  - Bacterial/Viral Panel
  - Parasite Panel

- **Hospital Acquired Infections**
  - MRSA

- **Respiratory Disease**
  - RVP-10 Panel
  - Pharyngitis Panel
TriageTrue® High Sensitivity Troponin

Bill Ferenczy
SVP, Cardiometabolic Business Unit
**Triage® Cardiac Marker Business Overview**

**Conditions:**
- **Heart Attack (MI)**
- **Heart Failure**
- **Thromboembolism**

**Cardiac Product Portfolio**

**Worldwide**
- Triage BNP Test
- Triage BNP for Beckman Coulter
- Triage D-Dimer Test
- Triage Cardiac Panel

**Outside US only**
- Triage NT-proBNP Test
- Triage Cardio2 Panel
- Triage Cardio3 Panel
- Triage Profiler SOB Panel
- **TriageTrue High Sensitivity Troponin I**

**Strong player in heart failure and thromboembolism:**
- Triage® NP and d-dimer assays best fit in **POCT and low volume settings**
- Triage® BNP CLIA-waiver expands availability to more clinics
- BNP for Beckman Coulter addresses automated **high-volume settings**
- COVID driving awareness and demand for rapid d-dimer testing

**Multiplex panels differentiate Triage® in OUS markets**
- Hospital/POCT in China
- Clinic based testing in Europe

**Challenge: market transition to high-sensitivity troponin**
- Continuous evolution of troponin assays that run on “big iron” analyzers
- Significant sensitivity gap between these assays and Triage/other POC tests
- OUS: Longtime hsTn availability has greatly reduced ER POCT
- Ongoing adoption in US a threat to Triage over next 5 years

**Opportunity: TriageTrue™ high sensitivity troponin**
Evolution of cardiac troponin assays

Troponin is released when heart muscle is injured

Levels: very low in healthy people to very high in MI patients

In chronic disease, levels are elevated but stable

In acute events such as MI, levels rise quickly and then fall

Early troponin assays

Specific, but not sensitive

If detected, interpretation easy = MI

But when not detected, challenging:

- Acute coronary syndrome can not be ruled out
- Patients often held for 12+ hours to allow time for Tn to rise to a detectable level
- Many patients unnecessarily admitted

High sensitivity troponin assays

- Very sensitive and accurate
  - Detect troponin in ≥50% of normal healthy people
  - Very precise even at low concentrations

Easy, if Tn not detected or below $99^{th}$ % = no MI

But, rule-in more difficult since Tn detected in many non-MI patients

Addressed with algorithms that combine Tn level and change over time
Myocardial infarction Dx algorithms

- ECG
- "Chest Pain" Patients
- Serial troponin testing
  - 0h 1h 2h 3h 4h 5h 6h

- ST Segment Elevation MI (STEMI)
  - Diagnostic = 5%
  - Non-diagnostic = 95%
- "Cath Lab" < 60 min
- Possible non-ST elevation MI (NSTEMI)
- Rule-in
- Observe
- Rule-out

"Chest Pain" Patients

0h 1h 2h 3h 4h 5h 6h
With hsTn, diagnosis is faster and safer

“Chest Pain” Patients

ECG

ST Segment Elevation MI (STEMI)
Diagnostic = 5%
Non-diagnostic = 95%

Possible non-ST elevation MI (NSTEMI)

Rule-in

Serial troponin testing
0h 1h 2h 3h 4h

Observe

Rule-out

25-40%

Shorter time between draws / faster decisions / fewer observation patients / 99% NPV for rule-out patients

“Cath Lab”

< 60 min

Rule-in

0h 1h 2h 3h 4h

Rule-out

Observe
Why POCT?

"Faster is Better": Reduce time to patient disposition 33-50% by eliminating time to transport/receive/process samples in central lab.
POCT in busy EDs: reduce total time to patient disposition:

- Allows clinicians to focus on the right patients
- Increases ED throughput and efficiency
- Greater patient satisfaction

Simpler and more cost-effective approach for low volume testing in the laboratories of small hospitals with fewer chest pain presentations.

“Democratization” of hsTn testing to urgent care centers and other non-hospital sites by enabling safe, rapid disposition of low-risk chest pain patients

**But can a POC assay meet the challenging hsTn analytical and clinical requirements established by central lab analyzers?**
**TriageTrue® High Sensitivity Troponin I Test**

**Runs on Existing Triage® MeterPro**
- True hsTnI performance
- Whole blood or plasma specimens
- Simple procedure
- Results in <20 minutes

**New Cartridge Design Drives Improved Sensitivity and Precision**
- Improved microfluidics slow and control flow through the diagnostic lane
- Improved filtration system reduces variation
- Control spots normalize signal and help eliminate background noise
Launch Strategy Guided by KOL Advisors

Multiple reviews of product performance and go-to-market strategies

Recommendation: Controlled market launch based on regulatory trial timing and scientific studies critical to market adoption:

1. Obtain CE Mark and execute a structured launch in Europe as fastest path to market and to gain real-world experience
2. Conduct major scientific study to validate assay clinical performance prior to initiating expensive, complex FDA trial
3. Leverage published study to fully drive market adoption OUS while the FDA trial underway
TriageTrue® Launch Timeline

2018

2019

2020

2021

2022

2023

2024

CE Mark / Targeted Euro Launch

APACE Study
APACE prospective international multicenter study
Clinical performance: 1,261 “suspected MI” patients:
- Fully adjudicated Dx by two cardiologists
- Comparison to Roche and Abbott hsTn assays
Outstanding results evidenced by validation of a safe and effective 0/1-hour algorithm
- Very high rule-out safety: 100% sensitivity
- No adverse events at 30 days in rule-out patients
- High rule-in accuracy:
- High efficacy: 74% of patients ruled in or out at 1 hour. Only 26% held for observation

Conclusion:
“POC-hs-cTnI TriageTrue® provides very high diagnostic accuracy in patients with suspected MI. Its clinical performance is at least comparable to that provided by the best validated central laboratory-based assays.”
TriageTrue® performance in APACE Study

CENTRAL ILLUSTRATION  Performance of the Point-of-Care High-Sensitivity Cardiac Troponin I TriageTrue Assay in Patients With Suspected Myocardial Infarction

1,261 Patients
With Suspected Non-ST-Segment Elevation Myocardial Infarction (NSTEMI)

Point-of-Care High-Sensitivity Cardiac Troponin I
Measured at 0 h and at 1 h

Triage by Single Cut-Offs

Direct Rule-Out
At 0 h <3 ng/l
45%

Direct Rule-In
At 0 h >60 ng/l
11%

Triage by 0/1-Hour Algorithm

Rule-Out
At 0 h <4 ng/l OR
At 0 h <5 ng/l AND
Delta 1 h <3 ng/l
55%

Observe
Others
26%

Rule-In
At 0 h ≥60 ng/l OR
Delta 1 h ≥8 ng/l
18%

NPV: 100% (99.4%-100%)
Sens: 100% (98.0%-100%)
Spec: 97.1% (95.9%-98.0%)

NPV: 100% (98.8%-100%)
Sens: 100% (95.9%-100%)
Spec: 95.0% (92.5%-96.8%)

All-Cause Death of Patients Ruled-Out by the 0/1 h-Algorithm
0% at 30 Days and 1.6% at 2 Years of Follow-up

TriageTrue® now included in European Society of Cardiology Guidelines for 0h/1h and 0h/2h algorithms

<table>
<thead>
<tr>
<th>0 h/1 h algorithm</th>
<th>Very low</th>
<th>Low</th>
<th>No 1hΔ</th>
<th>High</th>
<th>1hΔ</th>
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<tbody>
<tr>
<td>hs-cTn T (Elecsys; Roche)</td>
<td>&lt;5</td>
<td>&lt;12</td>
<td>&lt;3</td>
<td>≥52</td>
<td>≥5</td>
</tr>
<tr>
<td>hs-cTn I (Architect; Abbott)</td>
<td>&lt;4</td>
<td>&lt;5</td>
<td>&lt;2</td>
<td>≥64</td>
<td>≥6</td>
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<tr>
<td>hs-cTn I (Centaur; Siemens)</td>
<td>&lt;3</td>
<td>&lt;6</td>
<td>&lt;3</td>
<td>≥120</td>
<td>≥12</td>
</tr>
<tr>
<td>hs-cTn I (Access; Beckman Coulter)</td>
<td>&lt;4</td>
<td>&lt;5</td>
<td>&lt;4</td>
<td>≥50</td>
<td>≥15</td>
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<tr>
<td>hs-cTn I (Clarity; Singulex)</td>
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<td>&lt;2</td>
<td>&lt;1</td>
<td>≥30</td>
<td>≥6</td>
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<td>≥4</td>
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<td>≥90</td>
<td>≥20</td>
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<tr>
<td>hs-cTn I (TriageTrue; Quidel)</td>
<td>&lt;4</td>
<td>&lt;5</td>
<td>&lt;3</td>
<td>≥60</td>
<td>≥8</td>
</tr>
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<table>
<thead>
<tr>
<th>0 h/2 h algorithm</th>
<th>Very low</th>
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<tr>
<td>hs-cTn T (Elecsys; Roche)</td>
<td>&lt;5</td>
<td>&lt;14</td>
<td>&lt;4</td>
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<td>&lt;2</td>
<td>≥64</td>
<td>≥15</td>
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<tr>
<td>hs-cTn I (Centaur; Siemens)</td>
<td>&lt;3</td>
<td>&lt;8</td>
<td>&lt;7</td>
<td>≥120</td>
<td>≥20</td>
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<tr>
<td>hs-cTn I (Access; Beckman Coulter)</td>
<td>&lt;4</td>
<td>&lt;5</td>
<td>&lt;5</td>
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<td>≥20</td>
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<td>hs-cTn I (Clarity; Singulex)</td>
<td>&lt;1</td>
<td>TBD</td>
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<td>hs-cTn I (Vitros; Clinical Diagnostics)</td>
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<tr>
<td>hs-cTn I (Pathfast; LSI Medience)</td>
<td>&lt;3</td>
<td>TBD</td>
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<tr>
<td>hs-cTn I (TriageTrue; Quidel)</td>
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<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
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TriageTrue® Launch Timeline

2018: CE Mark / Targeted Euro Launch
2019: APACE Study
2020: US FDA Clinical Trial/Submission
2021: Leverage APACE / Expand OUS Efforts
2022: US Launch
2023: Additional Marketing/Scientific Studies
2024:
<table>
<thead>
<tr>
<th>Number of Patients Suspected of ACS</th>
<th>Annual Test Volume</th>
<th>TriageTrue® Price per Test – High vs Low</th>
<th>Potential Market</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>20M</strong> High estimate</td>
<td>Tests per Patient</td>
<td>Tests per Year</td>
<td></td>
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<tr>
<td>2 Tests</td>
<td>40M</td>
<td>$15</td>
<td>$540M $480 to $600</td>
</tr>
<tr>
<td><strong>15M</strong> Base estimate</td>
<td>Tests per Patient</td>
<td>Tests per Year</td>
<td></td>
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<tr>
<td>2 Tests</td>
<td>30M</td>
<td>$15</td>
<td>$405M $360 to $450</td>
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# TriageTrue® Targets

**“Research”**
- Pharma Company
- Academic/University
- LabCorp/Quest/ARUP/etc.
- Public Health
- IDN Care Lab

**“Reference Labs”**
- Large Hospital Lab
- Small Hospital Lab
- Micro Hospital Lab
- Free-Standing ER

**“Hospitals”**
- Urgent Care Center
- Physician Clinic
- Public Health Clinic
- Retail Clinic & Pharmacy

**“Ambulatory Care”**
- Long-term Care Center

**Target Segment** | Positioning | Opportunities (US) | Assumptions |
--- | --- | --- | --- |
Small & Micro Hospitals (In the Lab) | Most convenient and cost-effective approach for low volume testing | 3500+ hospitals (< 200 beds) 100 micro hospitals with number growing steadily | Secure existing accounts and quickly convert new accounts to gain solid share in segment |
POCT in ED | Faster disposition of patients in busy, high volume facilities | 1500 hospitals with busy emergency departments | Fewer targets and longer sales cycle, but very high volume per site |
Free Standing EDs | Faster disposition and cost/test at low volumes | 500+ facilities | Secure and expand share with significant penetration |
Urgent Care Centers | Rapid and convenient rule-out for low-risk patients. Help decompress busy nearby EDs | 10,000 locations. Most do not handle suspected MI cases today due to “liability”, but hsTn offers potential for safe, rapid disposition | Market development required – initial adoption slow, but can expand quickly via large multi-site UCC chains |
Ambulance | Rapid rule-out. Transport to appropriate facility. | TBD | First need proof of performance in moving vehicles. |

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*Ambulance*
Hospital Penetration Key to Success

Positioning and penetration based on number of beds per hospital

Good penetration in small hospitals
- Shorter sales cycle
- Testing done in lab
- TriageTrue is more cost effective
- Rapid uptake
- Low volume/site

Limited penetration in large hospitals
- Longer sales cycle
- Testing in the ED
- Triage speeds patient disposition
- High volume/site
- Support with outcome studies

Penetration by Number of Beds (US)
What We Believe We Can Get

Based primarily on US and Europe
- Well developed hsTn markets
- TriageTrue fit across multiple target segments
- Adequate reimbursement
- Hospital biggest segment but growing contribution from other settings
- Includes some pull through of other Triage tests

China opportunity TBD
- hsTn market still at early stages
- Hospital centric market
- Registration challenges and timing
- Current Triage business already at POCT and/or in higher volume settings – at outset TriageTrue would likely cannibalize existing business

Very limited revenue from ROW at this point
In the near-term, we’re building a highly competitive GI portfolio with distinct advantages.

Market potential of a global GI portfolio

<table>
<thead>
<tr>
<th></th>
<th>North America</th>
<th>Europe</th>
<th>APAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>C. difficile</td>
<td>35%</td>
<td>43%</td>
<td>42%</td>
</tr>
<tr>
<td>Shiga toxin</td>
<td>5%</td>
<td>4%</td>
<td>9%</td>
</tr>
<tr>
<td>Parasite Panel</td>
<td>8%</td>
<td>8%</td>
<td>9%</td>
</tr>
<tr>
<td>h. Pylori</td>
<td>23%</td>
<td>5%</td>
<td>6%</td>
</tr>
<tr>
<td>Campylobacter</td>
<td>16%</td>
<td>15%</td>
<td>28%</td>
</tr>
<tr>
<td>Intestinal Inflammation</td>
<td>13%</td>
<td>25%</td>
<td>5%</td>
</tr>
</tbody>
</table>

$400M  $300M  $200M

- We expect Sofia® C.diff performance to compare favorably with the leading visual immunoassay in the market while providing much needed improvements to workflow and data management.
- Our H.pylori stool antigen assay will target a market dominated by a single player.
- Other GI products will also benefit from Sofia’s platform features including objectivity, connectivity and performance over culture and visually read assays.

Sources: GHX, IDMM, Transparency Market Research, Competitive company annual reports
We are confident in our ability to launch a more cost-effective Strep A test...

...and we believe Sofia can capture roughly 25% to 30% of this volume

<table>
<thead>
<tr>
<th></th>
<th>Low</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>US annual rapid Strep A test volume&lt;sup&gt;1&lt;/sup&gt;</td>
<td>36 million</td>
<td>44 million</td>
</tr>
<tr>
<td>% of tests run on pediatric patients&lt;sup&gt;2&lt;/sup&gt;</td>
<td>80%</td>
<td>90%</td>
</tr>
<tr>
<td>% of tests reflexed to culture confirmation&lt;sup&gt;3&lt;/sup&gt;</td>
<td>70%</td>
<td>90%</td>
</tr>
<tr>
<td>Sofia 2 Strep A98 Price&lt;sup&gt;4&lt;/sup&gt;</td>
<td>...if $3.50</td>
<td>...TBD</td>
</tr>
<tr>
<td>Potential annual revenue</td>
<td>~ $35M</td>
<td>TBD</td>
</tr>
</tbody>
</table>

Range of revenue estimates driven by uncertain reimbursement scenarios

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1. GHX data for rapid Strep A tests sold through distribution. Annual Strep A market volume does experience some volatility.
2. VOC. Most tests performed on children (5-18yrs).
3. VOC / field sales. Not all physicians are backing up negatives. Some portion of physicians will treat empirically.
4. Distributor Transfer Price. Variance based on existing (base case) vs. higher (aspirational case) reimbursement.
Despite a significant drop in PCP visits due to COVID, we’ve continued driving awareness.
> 600 customers and counting!
Sofia’s future remains bright.

Planned product launches

- Strep 98
- c.Difficile
- Campylobacter
- h.Pylori
- Lactoferrin
- Shiga Toxin
- Parasite Panel

Areas of high interest

- Inflammation
- Infectious diseases
- TOX / DOA
- Allergy
- STIs
- UTI
COVID-19 Growth Drivers

Doug Bryant, President & CEO
In addition to the 4 COVID assays already launched, we continue to invest in R&D to fully address the urgent need.

COVID Assays in Development

1. **QuickVue**
   - SARS Antigen for professional use
   - In EUA Review 10/16/20

2. **Solana**
   - SARS-CoV-2
   - Target EUA submission 11/13/20

3. **Lyra**
   - Flu + SARS (Extracted)
   - Target EUA submission 11/30/20

4. **QuickVue**
   - SARS Antigen for at-home use
   - Target EUA submission 12/2020

5. **Sofia 2**
   - SARS-CoV-2 Antibody
   - Target EUA submission 12/2020

6. **Lyra**
   - Direct Flu + SARS
   - Target EUA submission 1/2021

7. **Savanna**
   - SVP4 (Flu A, Flu B, RSV and SARS)
   - Target EUA submission Q1/2021

8. **Sofia 2**
   - RVP4
   - Target EUA submission Q3/2021
“Sniffles” Platform

Karen Gibson
SVP, Digital Health
COVID has changed diagnostic testing forever

- Pandemic has highlighted the need for affordable and scalable diagnostic testing
- New patient care delivery models have exploded, but they still lack the ability to diagnose with certainty. Diagnostic testing is a huge value-added service to improve the provider and patient experience
- Healthcare industry and regulatory agencies are adopting new technology at faster pace than ever before … it is becoming the norm
- Diagnostics is becoming digitized

McKinsey Telehealth Survey

1 Consumer

2 Provider

3 Regulatory

Types of services available for telehealth have greatly expanded, with the Centers for Medicare & Medicaid Services (CMS) temporarily approving more than 80 new services and lifting restrictions on originating site, allowing Medicare Advantage plans to conduct risk assessments via telehealth, and adding other regulatory flexibilities to increase access to virtual care.

References:
4 Ibid
Introducing project ‘Sniffles’

- A small diagnostic device (about the size of a Grande coffee cup) able to read a standard Sofia Fluorescent Immunoassay Cartridge

- Images of the cassette are captured on the Sniffles device and transmitted via Bluetooth to a mobile device

- The result is then interpreted using a proprietary AI software model that is downloaded to a mobile device.
Benefits of ‘Sniffles’ platform

**Affordability**
- Sniffles device costs <20% of Sofia 2 to manufacture

**Mobility/Connectivity**
- Cellular connectivity enables testing in new markets beyond traditional Point of Care
- Will integrate results to proprietary Virena data management and other software platforms

**Scalability**
- 3rd party to manufacture 100K+ devices; Delivered in Q1 ’21
- Expansion capabilities to 1M+
‘Sniffles’ has broad application

Location of Activity

Sample Collection | Test Run | Results Interpretation | Clinician Counseling

Segment

Professional

Telemedicine Enabled

At-Home

Market Applications
- Physician Office
- Occupational Health
- Concierge Medicine
- Travel, Employer,
- Entertainment, etc.
- Telemedicine
- Consumer

Legend:

Performed at provider
Performed in home
“Sniffles” go-to-market strategy

**Phase 1: Leverage Mobility**
Fill market gaps to incorporate diagnostic testing.
Capture new market segments for testing by leveraging mobile technology and connectivity. Occupational health, employers, travel, etc.
Enable diagnostic testing with telehealth for full virtual patient care experience.

Early 2021

**Phase 2: Scale Professional Segment**
Allows testing to scale across the professional segment.
Add software features for professionals to engage physician offices, urgent cares, pharmacies, etc.

Late 2021

**Phase 3: Test at Home?**
Explore the possibility of home testing with an instrumented device: chronic conditions, etc.

TBD
Big Ideas

Werner Kroll, PhD
SVP, Research & Development
Leapfrog digital immunoassay technology enables earlier detection of acute infections and the paradigm shift to preventative in vitro diagnostics personalized healthcare of chronic diseases.

The health / disease continuum

Changes on health/disease status are most directly reflected by protein levels. Early detection which requires lower marker concentration to be detected allow to slow, stop or even reverse the progression of chronic diseases.
The earlier a diagnosis is achieved, and intervention initiated, the lower the overall treatment cost.

Since biochemical changes are small at early disease stages, more sensitive detection methods are required.

Innovative product developments combined with systematic evolutionary improvements of successful product lines

- **Original Lateral Flow Immunoassay concept**
- **CLIA waived, fast, visual read out**

**QuickVue**

- Improved objective performance: Instrument read lateral flow results
- Improved analytical sensitivity through fluorescent dyes

**Sofia**

- Improved affordability, connectivity and scalability
- Multiplexed immunoassays

**Sofia 2**

**Sniffles**

- Ultrasensitive immunoassay platform for the next decade
- Incremental technology improvements
- Disruptive technology improvement
Develop next generation ultrasensitive immunoassay technology to enable

- Significant improvement in earlier detection of acute infections
- Detection of pre-symptomatic concentrations of disease marker changes
- CLIA waived applications

Product features and drivers

Technology Performance Requirements

- Ultrahigh sensitivity: digital immunoassay (single fg/ml)
- Fast time-to-result
- Multiplexing
- Integrated sample handling and introduction
- Self learning cell algorithms for improved readout
- CLIA waivable technology
- Full mobility and connectivity
- POC compatible low-cost platform
- Modular manufacturing
Localized plasmon resonance as basis of disruptive digital point-of-care immunoassay technology

New methodology provides improved signal to noise ratio and provides LoD in low fg/ml concentration range

- Darkfield image of sensor after interaction with analyte specific nanoparticles marked antibodies
- When the analyte concentration is higher, a switch to analogue signal measurement extends the dynamic range of the assay
Demonstration of feasibility

Application of ultrasensitive immunoassay for troponin I allows expansion of clinical use and significant reduction of treatment cost

- Our TNI feasibility assay provides robust LOD in the double digit fg/ml level and an LoQ of about 250 fg/ml with CVs of less than 10 %

- The dynamic range spans 6 logs allowing the coverage of rule in and rule out application without dilution
Based on the demonstrated performance the assay can be used for effective rule out of MI in the ER and allows for faster discharge of about 45% to 55%* of suspected MI cases and thereby significant cost savings.

Sample to result process: The disruptive technology must deliver a complete solution

Individual process steps contribute differently to clinical performance

**Sampling**
Solutions for sampling of all easily accessible matrices will be developed and integrated in workflow
- Urine
- Fingerstick blood
- Saliva
- Swabs

**Sample Preparation**
Sample pretreatment and metering integrated in sampling device or assay cartridge; no manipulation required by user

**Sample Analysis**
Sample analysis in fully automated device enabling interaction with ready to use reagents without any manual handling. All reagents in cartridge.

**Data Analysis**
Instrument based data analysis.
Self learning AI via cloud access improves data analysis

**Communication**
Broad communication features supporting advanced e-health requirements
Integration of mature AI models supporting consumer guidance
Financial Update / M&A

Randy Steward, CFO
Transformational Years for Quidel

2017 purchased Cardiometabolic Business from Abbott
- Global commercial enterprise – sell in >100 countries
- Global management and infrastructure capabilities
- Expanded revenues, earnings and cash flows

2020 SARS product launches
- R&D capabilities – first with Antigen and Flu/SARS combo
- Operations expertise in ramping production
- Rapid action on global supply chain

Quidel Revenue and EBITDA
Quidel Immunoassay Capacity Build

Current path to capacity expansion

- Maximized initial Sofia production at 1.8M tests weekly
- Converted existing manufacturing lines to achieve 2.1M tests weekly
- Committed $70M to add four additional manufacturing lines to achieve a minimum of 4.8M tests weekly
- Adding QuickVue dipstick pouch to double capacity to 2.0M tests weekly
Line 7 Installation
New Distribution Site
Quidel Molecular Capacity Build

- April 2020 ramped up capacity to 480K tests per week
- Through several process improvement initiatives increased capacity to 690K tests per week
- Adding new lyophilization equipment December 2020 to increase capacity to 940K tests per week
Strong Quidel Revenue Growth

**Short-term**
- Exit 2020 with Sofia install base @ 75,000 creating a larger customer base for respiratory menu
- Expanded Sofia menu, Gastrointestinal, Strep98, others

**Medium-term**
- Savanna launch 2H21 with respiratory panel
- hsTnl clinical trials in 2021

**Long-term**
- Savanna menu expansion
- US Launch for hsTnl

![Quidel Core Non-COVID Business Growth Trend](image)

- 18% CAGR
- QDEL Other
- Cardiometabolic
- Sofia
- Savanna
## Capital Structure

<table>
<thead>
<tr>
<th>Debt Type</th>
<th>Initial Date</th>
<th>Amount</th>
<th>Balance at 12/31/2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Convertible Bond Debt</td>
<td>December 2014</td>
<td>$172.5 million</td>
<td>$0</td>
</tr>
<tr>
<td>Term Loan Debt</td>
<td>October 2017</td>
<td>$245 million</td>
<td>$0</td>
</tr>
<tr>
<td>Revolver Debt</td>
<td>October 2017</td>
<td>$10 million</td>
<td>$0</td>
</tr>
<tr>
<td>Deferred &amp; Contingent Consideration (Abbott)</td>
<td>October 2017</td>
<td>$280 million</td>
<td>$136 million</td>
</tr>
</tbody>
</table>

- De-levered from >$700M debt to $136M in just over 3 years
- Consummated sale-leaseback transaction for $146 million in January 2018
- Repurchased >96% of convertible bonds prior to maturing (weighted avg price of $61.43)
- Utilized cash flow from operations to reduce loan debt and contingent consideration
- Strong balance sheet – positioned for future investment opportunities
M&A can further enable our strategy

We have three criteria against which we are constantly evaluating opportunities

---

**Strategic Fit**

- Leverages existing assets
  - R&D capabilities
  - Existing sales call points and distribution partners
  - Sofia installed base
- Platform for future growth
  - New/adj market segments
  - Product portfolio extends
  - Production capacity
- Secures supply chain

---

**Financial Fit**

- Accelerate top-line growth
- Margins
  - ~65% product GM
  - ~35% EBITDA
- ROIC

---

**Ability to Execute**

- Integration assessment
- Confidence in achieving synergies
Goals for 2021

- Increase R&D investment in support of LRP growth initiatives
- Successfully launch additional COVID-19 assays
- Meet production ramp targets
- Complete T2 clinical trials
- Pursue M&A transaction
- Commercialize Savanna®

Increase R&D Investment in support of LRP growth initiatives