

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**  
**Pursuant to Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934**  
**August 14, 2024**  
**Date of Report (Date of earliest event reported)**

**Biodesix, Inc.**  
(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-39659**  
(Commission  
File Number)

**20-3986492**  
(I.R.S. Employer  
Identification No.)

**919 West Dillon Rd.**  
**Louisville, Colorado**  
(Address of Principal Executive Office)

**80027**  
(Zip Code)

**Registrant's telephone number, including area code: (303) 417-0500**

**Not Applicable**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| <b>Title of each class</b>                   | <b>Trading<br/>Symbol(s)</b> | <b>Name of each exchange<br/>on which registered</b> |
|--|------------------------------|--|
| Common Stock, par value of \$0.001 per share | BDSX                         | The Nasdaq Stock Market LLC                          |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01. Regulation FD Disclosure.**

On August 14, 2024, the Company posted a corporate presentation in the “Investor Relations” portion of its website at <https://investors.biodesix.com/investor-relations>. A copy of its current corporate presentation is attached to this Current Report on Form 8-K as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

The information contained in this Item 7.01 and Exhibit 99.1 attached hereto is furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such document or filing.

**Item 9.01. Financial Statements and Exhibits.**

*(d) Exhibits:*

| <u>No.</u> | <u>Exhibit</u>  |
|------------|---|
| 99.1       | <a href="#">Corporate Presentation of Biodesix, Inc., dated August 14, 2024</a> |
| 104        | Cover Page Interactive Data File (embedded within the Inline XBRL document)     |

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: August 14, 2024

BIODESIX, INC.

By: /s/ Robin Harper Cowie

Name: Robin Harper Cowie

Title: Chief Financial Officer



# biodesix<sup>®</sup>

## Corporate Presentation

Biodesix is a blood-based lung diagnostic company addressing a large unmet need with limited competition



3Q24

## Disclaimer

This presentation and the accompanying oral presentation have been prepared by Bidesix, Inc. ("Bidesix", "we" or the "Company") for informational purposes only and not for any other purpose. Nothing contained in this presentation is, or should be construed as, a recommendation, promise or representation by the presenter or Bidesix or any officer, director, employee, agent or advisor of Bidesix. This presentation does not purport to be all-inclusive or to contain all of the information you may desire. Information provided in this presentation and the accompanying oral presentation speak only as of the date hereof.

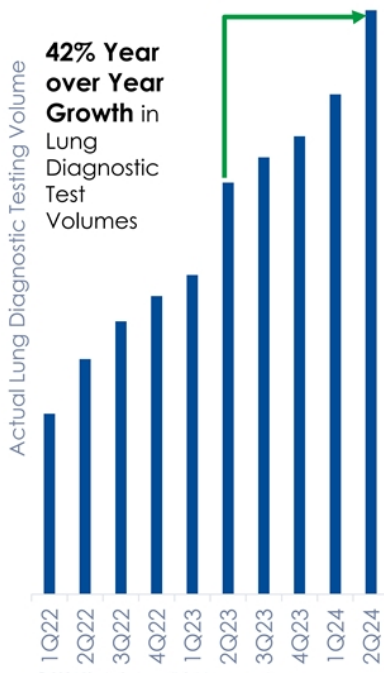
Certain information contained in this presentation relates to, or is based on, studies, publications, surveys and other data obtained from third-party sources and Bidesix's own internal estimates and research. While we believe these third-party sources to be reliable as of the date of this presentation, we have not independently verified, and make no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

This presentation contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this presentation, including statements regarding our future financial condition, results of operations, business strategy and plans, and objectives of management for future operations, as well as statements regarding industry trends, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "predict," "should," "will" or the negative of these terms or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, factors, and assumptions. Forward-looking statements may include information concerning, among other things, the impact of backlog and the timing and assumptions regarding collection of revenues on projections, availability of funds and future capital including under the term loan facility, the impact of a pandemic, epidemic, or outbreak of an infectious disease in the United States or worldwide, including the COVID-19 pandemic, our inability to achieve or sustain profitability, our unaudited financial statements including a statement that there is a substantial doubt about our ability to continue as a going concern and a continuation of negative financial trends potentially resulting in our inability to continue as a going concern, our ability to attain significant market acceptance among payers, providers, clinics, patients, and biopharmaceutical companies for our diagnostic tests, difficulties we may experience in managing our growth, our failure to retain sales and marketing personnel, and failure to increase our sales and marketing capabilities or develop broad awareness of our diagnostic tests to generate revenue growth, our failure to maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, significant fluctuation in our operating results, causing our operating results to fall below expectations or any guidance we provide, our product performance and reliability to maintain and grow our business, our vulnerability to supply problems and price fluctuations through third-party suppliers, including courier services, natural or man-made disasters and other similar events, including the COVID-19 pandemic, our failure to offer high-quality support for our diagnostic tests, which may adversely affect our relationships with providers and negatively impact our reputation among patients and providers, and our inability to continue to innovate and improve our diagnostic tests and services we offer. These risks and uncertainties are described in more detail under the caption "Risk Factors" in our filings with the Securities and Exchange Commission. In addition, new risks may emerge from time to time, and it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this presentation or to conform these statements to actual results or to changes in our expectations.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

# Execution play – First mover advantage addressing estimated 5 million patients at risk of having lung cancer



- **Large market:** Estimated 5 million patients with lung nodules with first mover advantage
- **Five reimbursed tests:** 5 blood-based Lung Diagnostic tests with Medicare coverage and various levels of private payer coverage
- **2Q24 Revenue growth over 2Q23:**
  - Total Revenue grew 51%
  - Lung Diagnostic revenue grew 44%
  - Biopharmaceutical Services revenue grew 228%
  - FY2024 Guidance increased to \$70-72 million from \$65-68 million
- **Strong gross margins:** 78.4% in 2Q24 – up 5.7% points vs. 2Q23
- **Path to profitability:** 2Q24 Net Loss improved by 19% and Adjusted EBITDA\* improved 38% over 2Q23 - Expecting positive Adjusted EBITDA in 2H25
- **Experienced team:** Extensive experience in diagnostics, reimbursement, regulatory, development, and commercialization

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\*For non-GAAP reconciliation, please see Quarterly Earnings Press Releases at [www.Biodesix.com](http://www.Biodesix.com)

## Two revenue growth drivers



### Lung Diagnostic Tests

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Focused on early diagnosis of lung cancer and personalized cancer treatment with best-in-class turn around times

### Biopharmaceutical and Diagnostic Services

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Biomarker discovery, assay design and development, clinical trial testing and support, companion diagnostic and IVD test development and commercialization for various tumor types and diseases

# Biodesix operates **two** certified, high-complexity laboratories



- ✓ **CAP**-accredited
- ✓ **CLIA**-certified
- ✓ **NYS CLEP** certified: Soluble Tumor Markers, Molecular & Cellular Tumor Markers and Virology
- ✓ **ISO 13485**-certified

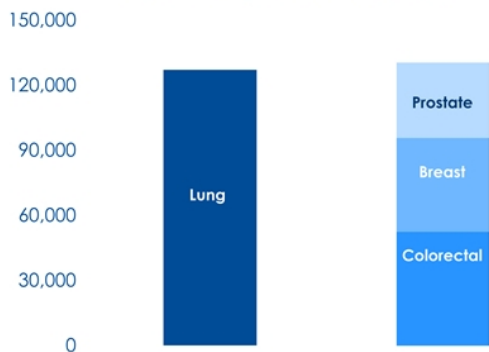


- ✓ **CAP**-accredited
- ✓ **CLIA**-certified
- ✓ **NYS CLEP** certified: Soluble Tumor Markers & Diagnostic Immunology
- ✓ **ISO 13485**-certified

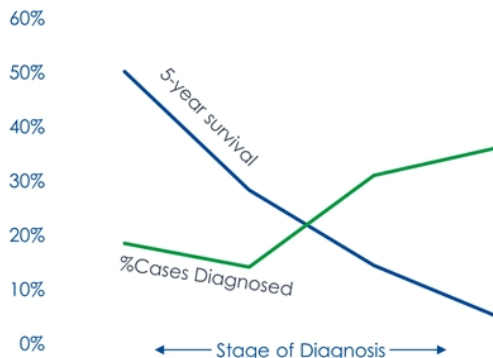


# Lung cancer is the **leading cause of cancer deaths**, but early detection saves lives

Lung cancer deaths versus colorectal, breast, and prostate combined<sup>1</sup>



Few patients are diagnosed early when survival is up to 10x greater



Only 5.8% of those eligible were screened

1 in 16 people will be diagnosed with lung cancer in their lifetime

5-year survival for metastatic cancer is only 6%

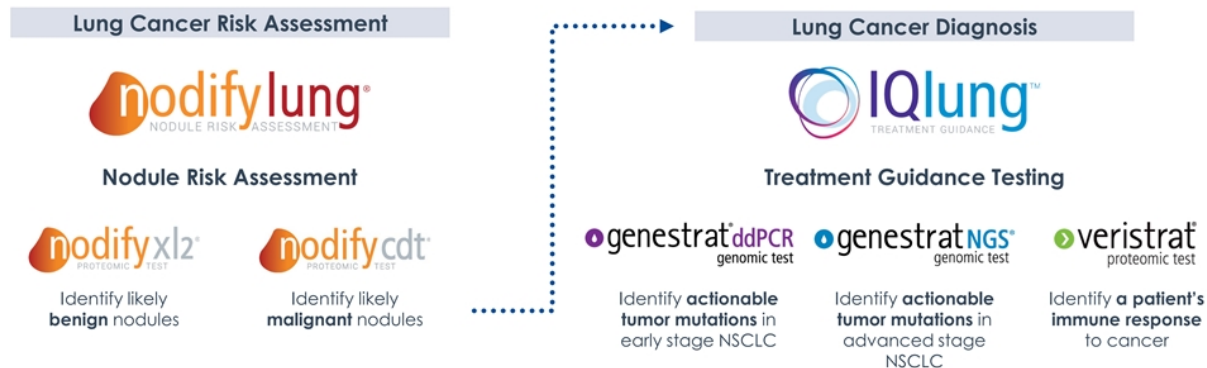
Deadliest of all cancers

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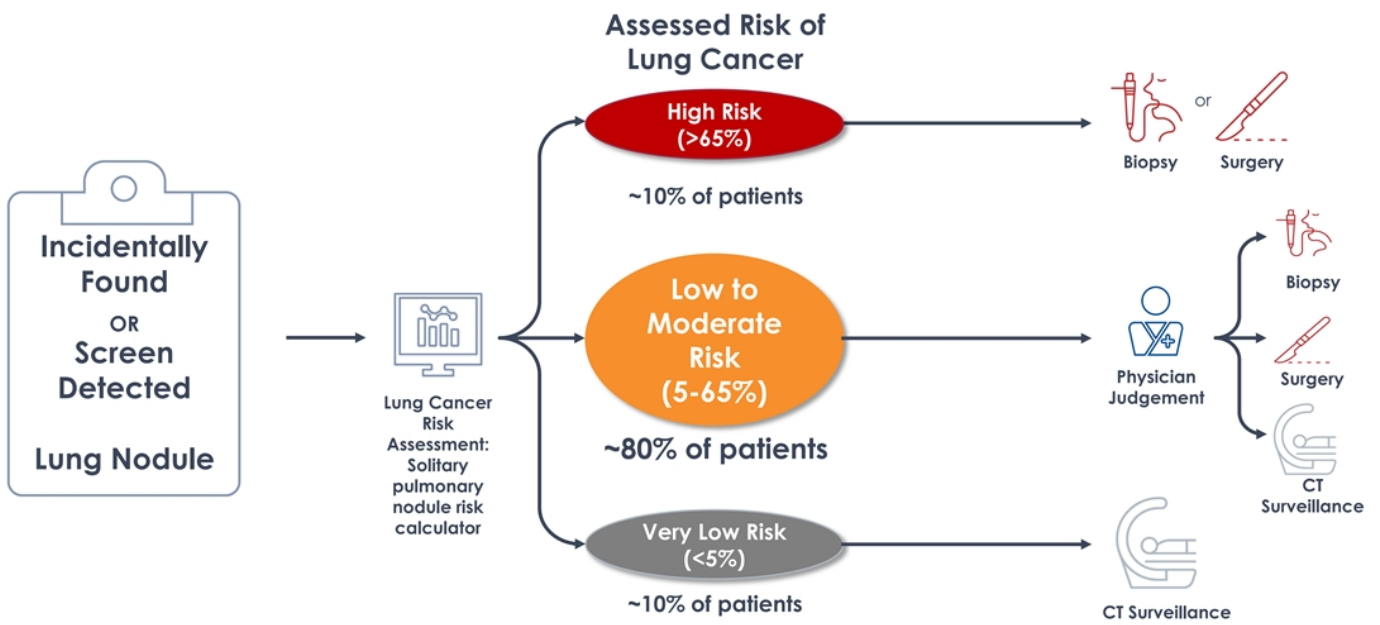
<sup>1</sup>2022E mortality in US (SEER)  
<sup>2</sup>2022 American Lung Association State of Lung Cancer Report

# Five blood-based Medicare covered tests for the same patient population with best-in-class turnaround times

## **biodesix**<sup>®</sup> Lung Diagnostic Testing Portfolio



# Standard of care: Guideline directed lung nodule management<sup>1</sup>



## Standard lung cancer risk assessment has led to **over- and under-treatment of patients**

**62%** 

of patients receiving biopsy as the sole diagnostic procedure were benign<sup>1</sup>

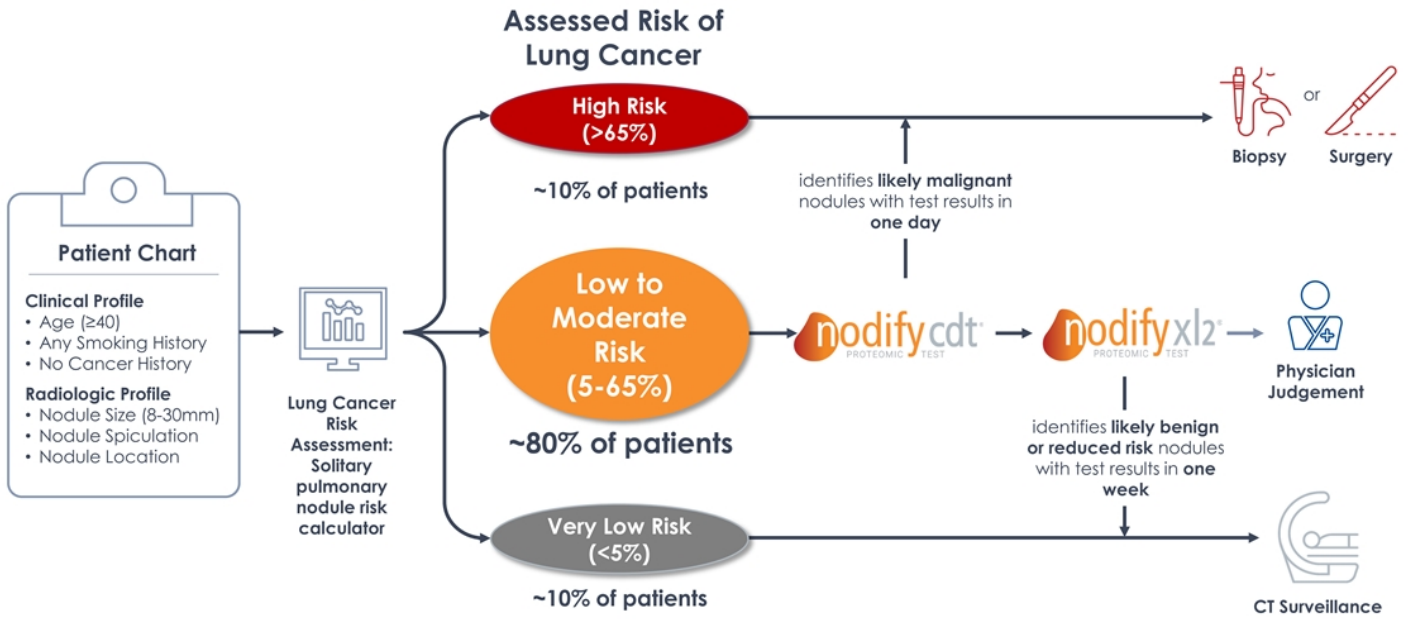
**35%** 

of patients who underwent surgery had benign nodules<sup>1</sup>

**17%** 

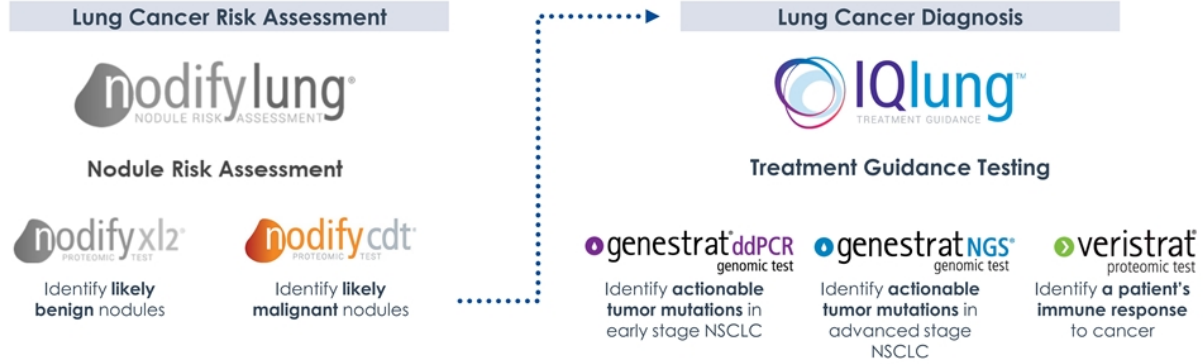
of patients sent to CT surveillance have malignant nodules<sup>2</sup>

# One blood draw, two tests to reclassify risk to help reduce uncertainty in lung nodule management



**Five Medicare covered tests** for the same patient population with best-in-class turnaround times

  
**Lung Diagnostic Testing Portfolio**



Testing helps guide the **right treatment to the right patient** as quickly as possible

~ **235k** 

patients diagnosed annually with NSCLC in the US<sup>1</sup>

**10.5 months** 

median overall survival of patients with advanced stage NSCLC<sup>2</sup>

**26 days** 

Length of time for turnaround for tissue testing<sup>3</sup>

*>60 treatments and combinations recommended by NCCN for patients with lung cancer<sup>4</sup>*

# Treatment guidance tests for all stages of lung cancer


## Early stage Lung Cancer

 **veristrat**  
proteomic test    Immune profiling test


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 **genestrat** **ddPCR**  
genomic test

## Advanced, metastatic, or recurrent Lung Cancer

 **veristrat**  
proteomic test    Immune profiling test

---

 **genestrat** **NGS**  
genomic test    52-gene test

Average turnaround time of 3 business days



# Robust pipeline to address additional clinical needs for the same patient population



# Biopharmaceutical and Diagnostic Services partnerships providing research, discovery, new test development, and clinical study testing

**\$8.1 M in Biopharma Services under contract but not yet recognized**

## Our Partners

ThermoFisher  
SCIENTIFIC

BIO-RAD

BRUKER

Memorial Sloan Kettering  
Cancer Center

STRECK

## Our Biopharma Partnerships

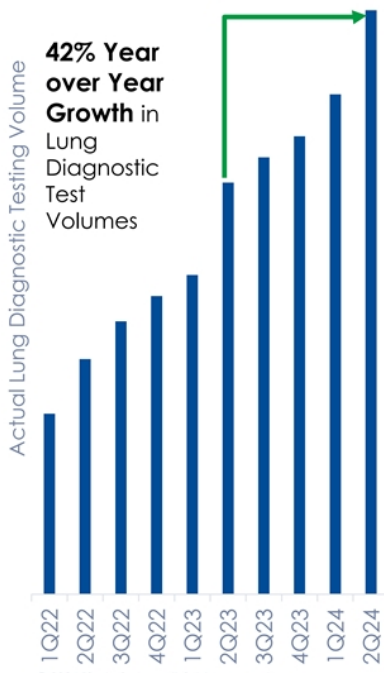
**60+**  
biopharma customers and  
academic partners

Partnerships with  
**9 of the Top 12**  
largest pharma companies  
by 2023 revenue

Select publicly-disclosed biopharma customers

AstraZeneca GSK  
Genentech Pfizer

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# Extensive knowledge and experience in diagnostics & reimbursement



Scott Hutton  
CEO

**Spectranetics**  
Always Reaching Further  
**Medtronic**



Robin Harper Cowie  
CFO

**Precision Therapeutics**  
The future of personalized medicine  
**UPMC**  
UNIVERSITY PITTSBURGH MEDICAL CENTER



Gary Pestano  
CDO (PhD)

**Roche** **VENTANA**  
**HARVARD MEDICAL SCHOOL** **Dana-Farber Cancer Institute**



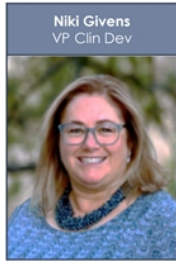
Kieran O'Kane  
CCO

**nanoString**  
**Eitest** **Roche**



Chris Vazquez  
CAO

**Sprint**  
**KPMG**



Niki Givens  
VP Clin Dev

**TERUMOBCT**  
Unlocking the Potential of Blood  
**University of Colorado**



Mark DeBlock  
VP Sales

**spiration**  
**HOLOGIC**



Steven Springmeyer  
CMO (MD)

**Indi**  
**spiration**



James Jeff  
CMO (MD)

**Oncimmune**  
**UPMC**  
**MAYO CLINIC**



Brianna Phillips  
VP Qual & Reg

**Medtronic**  
**COVIDIEN**

Thank you!



# Appendix





Ordered together - Run in sequence



Identifies patients with lung nodules that are **likely malignant**



**Autoantibodies** on an **ELISA platform** from **blood**  
P53 | CAGE | NY-ESO-1 | GBU4-5 | MAGE A4 | SOX2 | HuD



**78% PPV, 98% specificity** & 28% sensitivity



**1 business day** turnaround time



**Medicare and new Private Payer coverage** with a unique CPT code & ADLT status (\$649)



Identifies patients with lung nodules that are **likely benign**



**Proteins** on an **LC-MS platform** from **blood**  
*Proteins:* LG3BP | C163A  
*Clinical Profile:* Age | Smoking History | Cancer History  
*Radiologic Profile:* Nodule Size | Location | Spiculation



**98% NPV, 97% sensitivity** & 44% specificity



**4-5 business days** turnaround time



**Medicare and new Private Payer coverage** with a unique CPT code & ADLT status (\$3,520)

Two studies (ALTITUDE & ORACLE) for combined lung nodule risk assessment and over 50 peer-reviewed publications, presentations & abstracts

**genestrat<sup>ddPCR</sup>**  
genomic test



Identifies **blood-based, guideline recommended NSCLC tumor mutations**



BRAF, EGFR, KRAS, ALK



**91% sensitivity & 100% specificity**



**Average 2-3 business day** turnaround time



**Medicare and private payer coverage**  
Can be ordered multiple times per patient (~\$600 based on # genes ordered)

**genestrat<sup>NGS</sup>**  
genomic test



Identifies **blood-based, guideline recommended tumor mutations**



**52 genes** including somatic nucleotide variants, indels, copy number amplification and rearrangements



**95% sensitivity & 100% specificity**



**Average 2-3 business day** turnaround time



**Medicare and private payer coverage**  
One per patient per cancer per lifetime (\$2,919)

**veristrat**  
proteomic test



**Blood-based test** identifies a **chronic inflammatory disease state** associated with compromised immune system leading to poorer outcomes



**Proprietary proteomic signature** identified from **blood** by **MALDI-ToF Mass Spectrometry**



VeriStrat Good test result (**2x median overall survival**) vs. VeriStrat Poor test result



**Average 2-3 business day** turnaround time



**Medicare and private payer coverage** with a unique CPT code & ADLT status (\$2,871)

**Greater than 4,500+ patients** enrolled in INSIGHT<sup>1</sup> prospective clinical utility study



## In-Office Blood Collection with Tasso+ Capillary Device



### Impact to Lung Nodule Patient Care

- Single-use blood lancing device intended for obtaining capillary whole blood samples from a patient's upper arm
- FDA Class II Lancet 510(k) cleared
- Improves patient access to Nodify Lung® testing in practices without convenient access to venous draw services
- Administered in minutes by any healthcare provider without need for venipuncture
- Virtually painless sample collection
- Improves care delivery by accelerating time to results and preventing patients from making a second trip to have blood drawn

"Oneida Health is a referral center serving patients in a wide geographical area. This device has allowed us to order Nodify Lung testing when patients are here for visits, ensuring that we get the critical information to inform the shared decision-making process quickly and accelerate the time to diagnosis."

- Pedro Del Pino, MD, Oneida Health

## Intellectual property portfolio



**>100 issued patents**  
US and foreign

### Patent Subject Matter:

- VeriStrat® and Nodify® tests and their uses in non-small cell lung and other diseases (e.g., breast cancer, prostate cancer, liver cancer, graft v. host disease)
- DeepMALDI mass spectrometry methods
- Classifier development using the Diagnostic Cortex® AI platform
- Pipeline tests using proteomic testing in immunotherapies
- Biodesix Blood Collection Device
- Proteomic drug-associated tests developed for our 3<sup>rd</sup> party partners



**25 unique registered and filed trademarks**  
across 11 countries

### Exemplary Issued Marks:

- Biodesix
- Biodesix Lung Reflex
- VeriStrat
- GeneStrat
- DeepMALDI
- Diagnostic Cortex
- ImmunoStrat
- Nodify
- Nodify Lung
- Nodify XL2
- Nodify CDT
- GeneStrat NGS

### Filed Marks:

- IQlung
- IQlung + Logo

## A Board of Directors with a vast amount of industry expertise

|  |   |   |   |
|--|---|---|---|
| <b>John Patience</b><br>CHAIRMAN                                   | Crabtree Partners LLC   | McKinsey & Company  |   |
| <b>Scott Hutton</b><br>PRESIDENT & CEO                             |  |   |    |
| <b>Hany Massarany</b><br>CHAIR - COMPENSATION COMMITTEE            |  |    |    |
| <b>Jean Franchi</b><br>CHAIR - AUDIT COMMITTEE                     |  |   |    |
| <b>Matt Strobeck</b><br>CHAIR - NOMINATIONS & GOVERNANCE COMMITTEE | Birchview Capital   | WESTFIELD CAPITAL MANAGEMENT  |    |
| <b>Jack Schuler</b>  |  |  |   |
| <b>Lair Kennedy</b>  |  |  |   |
| <b>Jon Faiz Kayyem, Ph.D.</b>                                      |  |    |   |
| <b>Charles Watts, M.D.</b>   |  |   |    |