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

September 9, 2021
Date of Report (Date of earliest event reported)

Biodesix, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-39659**	**20-3986492**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

2970 Wilderness Place, Suite 100 **Boulder, Colorado** (Address of Principal Executive Office)	**80301** (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:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
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 September 9, 2021, 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:

No.	Exhibit
99.1	Corporate Presentation of Biodesix, Inc., dated September 9, 2021
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: September 9, 2021

BIODESIX, INC.

By: /s/ Robin Harper Cowie
Name: Robin Harper Cowie
Title: Chief Financial Officer

Exhibit 99.1

biodesix®

Corporate Presentation

Third Quarter 2021

Disclaimer

This presentation and the accompanying oral presentation have been prepared by Biodesix, Inc. ("Biodesix", "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 Biodesix or any officer, director, employee, agent or advisor of Biodesix. 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 Biodesix'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, including among other things, the dependence of the commercial success of our current and future diagnostic tests and services on attaining significant market acceptance, difficulties we may experience in managing our growth, our failure to retain sales and marketing personnel and marketing capabilities or to develop broad awareness of our diagnostic tests, our failure to maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, the demand for, and increased adoption of, our diagnostic tests, including our COVID-19 tests, being lower than we anticipate, our dependence on third-party suppliers, competition in our industry and specifically in the diagnostic tests space, our failure to offer high-quality support for our diagnostic tests and services which may adversely affect our relationships with providers and negatively impact our reputation among patients and providers. 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.

Presenting today

Scott Hutton

President & Chief Executive Officer

20+ years of industry experience with expertise in
Leadership | Mergers & Acquisitions | Sales & Marketing

biodesix	Chief Operating Officer
Spectranetics	SVP & General Manager of the Vascular Intervention division
Medtronic	VP & General Manager of Neurosurgery VP & Business Leader of Surgical Navigation and Intra-Operative Imaging

Robin Harper Cowie

Chief Financial Officer

15+ years of industry experience with expertise in
Finance | Reimbursement | Operational Excellence

biodesix	VP of Finance VP of Reimbursement & Health Economics Senior Director and Director of Reimbursement
Precision Therapeutics	Director of Payor & Government Relations Manager of Business Development Planning & Analysis
UPMC	Former Laboratory Manager, Researcher

biodesix®

We strive to be a trusted partner that the world relies on for data-driven diagnostic solutions in lung disease by improving overall patient outcomes and lowering the overall healthcare cost by reducing the use of ineffective and unnecessary treatments and procedures.

Our Portfolio

We have **7** tests for **lung disease**

LUNG NODULES

Pulmonologists, Hospital Systems

nodify lung®
NODULE RISK ASSESSMENT

nodify xl2
PROTEOMIC TEST

Identify **likely benign** nodules

nodify cdt
PROTEOMIC TEST

Identify **likely malignant** nodules

LUNG CANCER

Pulmonologists, Thoracic Surgeons, Medical Oncologists

biodesix lung®
REFLEX

genestrat®
genomic test

Tumor genetic profile – **actionable tumor mutations**

veristrat®
proteomic test

Patients' **immune response** to cancer

RESPIRATORY VIRUSES

Hospital Systems, Employers, Universities, State of Colorado

biodesix WorkSafe™
COVID-19 TESTING PROGRAM

ddPCR Test*

MOLECULAR
viral RNA detection

Total Antibody Test*

SEROLOGY
IgG, IgM, IgA antibodies

cPass™ SARS-CoV-2 Neutralization Antibody Test

DETECTION
of SARS-CoV-2 neutralizing antibodies

*Commercialized in partnership with Bio-Rad Laboratories

Lung Cancer Continuum of Care

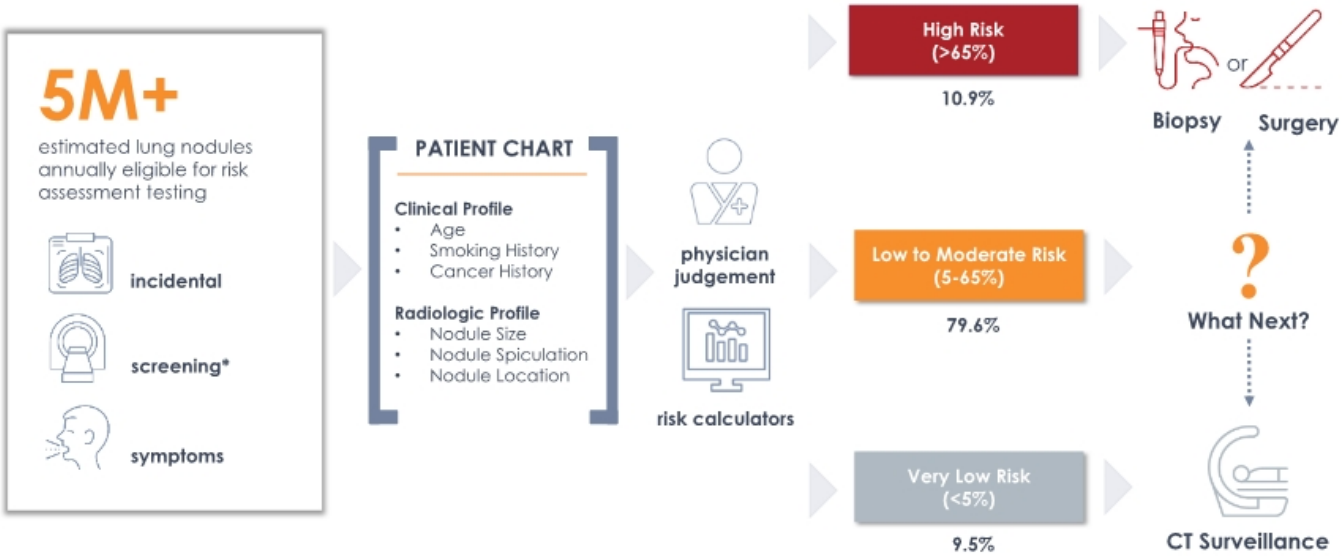
Identifying **clinical unmet needs** in patient care

DIAGNOSIS		TREATMENT	MONITORING
LUNG NODULE RISK ASSESSMENT pulmonologists	**CONFIRM DIAGNOSIS** pulmonologists, thoracic surgeons	**TREATMENT DECISIONS** medical oncologists, thoracic surgeons	**DISEASE RECURRENCE & PROGRESSION** medical oncologists, thoracic surgeons
How can we improve the risk assessment of suspicious lung nodules?	**17%** of patients sent to **CT surveillance** have **cancer** **62%** of **biopsies** are on **benign** nodules **35%** of **surgeries** are on **benign** nodules	**30-50%** of patients have **insufficient tissue** for molecular testing **9** -day **testing turnaround time** is too long to wait for treatment decisions How can we ensure the right patient gets the right treatment quickly?	**20-40%** of stage I NSCLC patients **recur** after curative-intent surgery How can we identify disease progression earlier?

Lung cancer kills more people annually in the US than the next three cancers combined (Colorectal, Breast, Prostate)

Diagnosis

Understanding lung nodule management



*USPSTF recently published a final recommendation statement to expand the eligible population for lung cancer screening (March 9, 2021). The recommendation expands the age range to 50 to 80 years (previously 55 to 80 years) and reduced the pack-year history to 20 pack-years of smoking (previously 30 pack-years).

nodify lung
NODULE RISK ASSESSMENT

Blood-Based Nodule Risk Assessment

nodify cdt
PROTEOMIC TEST

- 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
- **24-hour** turnaround time
- Full commercial launch **March 2020**
- Efforts ongoing with payers

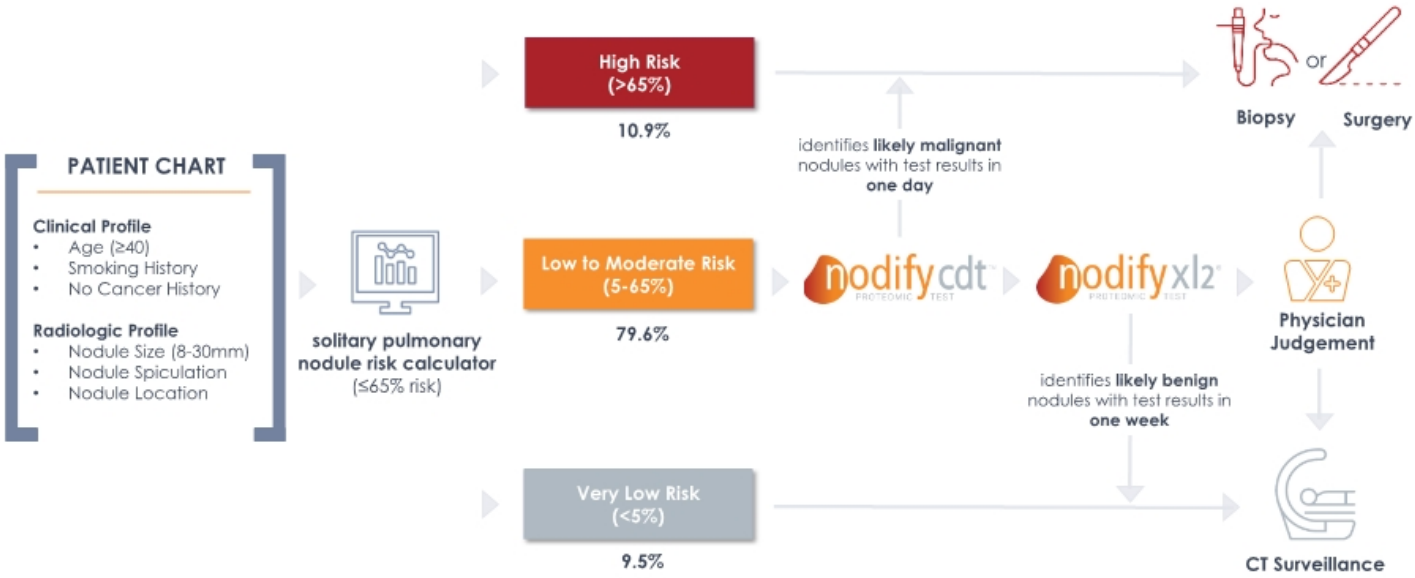
nodify xl2
PROTEOMIC TEST

- Identifies patients with lung nodules that are **likely benign**
- **Proteins** on an **LC-MS platform** from **blood (BCD)**
  Proteins: LG3BP | C163A
  Clinical Profile: Age | Smoking History | Cancer History
  Radiologic Profile: Nodule Size | Location | Spiculation
- **98% NPV, 97% sensitivity** & 44% specificity
- **4-day** turnaround time
- Full commercial launch **October 2019**
- **Medicare coverage** with a unique CPT code & ADLT status ($3,520)

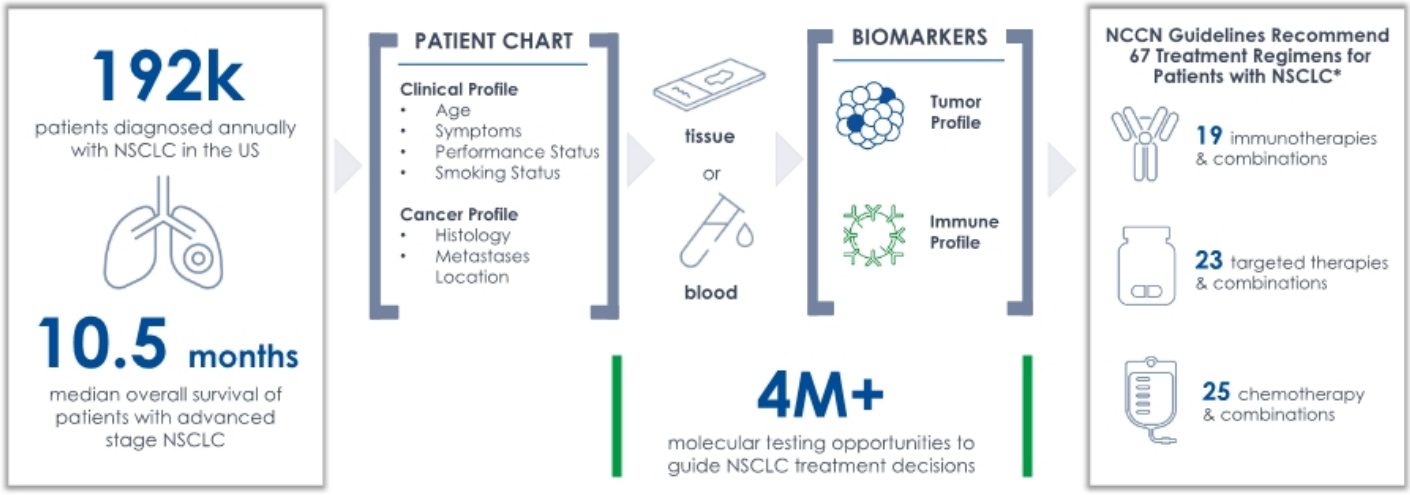
Two studies ongoing (ALTITUDE & ORACLE) for combined lung nodule risk assessment and over 35 peer-reviewed publications & abstracts

Diagnosis

Reclassifying risk to help reduce uncertainty in lung nodule management



Patients need to be given the right treatment as fast as possible



*In the NCCN Guidelines NSCLC v.1 2018, there were **34** treatment regimens (**4** immunotherapies**, **9** targeted therapies, **21** chemotherapies)

** On March 4, 2015, the first immunotherapy (nivolumab) was approved to treat patients with NSCLC

biodesix lung REFLEX

Blood-Based Tumor & Immune Profiling

genestrat genomic test

- Identifies **blood-based**, **guideline recommended NSCLC** tumor mutations
- **Mutations** detected by **ddPCR** from **blood**
  DNA (SNV/Indels): BRAF | EGFR | KRAS
  RNA (Fusions): ALK | RET | ROS-1
- **91% sensitivity** & **100% specificity**
- **Less than 36-hour** turnaround time
- **Medicare and private payer coverage**
  Not restricted by stage of NSCLC or multiple tests per patient per cancer
- **30+** publications & abstracts

veristrat proteomic test

- **Blood-based test** identifies a **chronic inflammatory disease state** associated with aggressive cancer
- **Proprietary proteomic signature** identified from **blood (BCD)** by **MALDI-ToF Mass Spectrometry** & **AI**
- VeriStrat Good (**2x median survival**) vs. VeriStrat Poor
- **Less than 36-hour** turnaround time
- **Medicare and private payer coverage**
  with a unique CPT code & ADLT status ($2,871)
- **85+** publications & abstracts

Greater than 4,000+ patients enrolled in INSIGHT[1] registry study

[1] https://clinicaltrials.gov/ct2/show/NCT03289780

Lung Cancer Continuum of Care

Where our peer-products fit along the patient treatment pathway

DIAGNOSIS		TREATMENT	MONITORING
LUNG NODULE RISK ASSESSMENT pulmonologists	**CONFIRM DIAGNOSIS** pulmonologists, thoracic surgeons	**TREATMENT DECISIONS** medical oncologists, thoracic surgeons	**DISEASE RECURRENCE & PROGRESSION** medical oncologists, thoracic surgeons
nodify lung nodify xl2 nodify cdt **DetermaDx** (Oncocyte) failed in validation **Nasal Brushing Classifier** (Veracyte) -earliest anticipated launch 2H 2021 -claims 'non-invasive' -population limited to current or former smokers -uncertain turnaround time	imaging (CT & PET) biopsy → **Percepta** (Veracyte) surgery	biodesix lung REFLEX genestrat genomic test veristrat proteomic test **biodesix NGS test** **Guardant360 CDx** (Guardant Health) **FoundationOne Liquid CDx** (Foundation Medicine) **FoundationOne CDx** (Foundation Medicine)	biodesix lung REFLEX genestrat genomic test veristrat proteomic test Imaging (CT & PET) symptoms

Pipeline Products

Next Generation Sequencing (NGS) 52-Gene Test

- Fastest test with 72-hour Turn-around time vs. 7-14 days, for guideline relevant mutations
- Synergies with existing GeneStrat ddPCR 6-gene test and VeriStrat tests
- Launch now expected first quarter of 2022

Risk of Recurrence Test (RoR)

- Host immune profiling signature that identifies stage 1 NSCLC patients pre-surgery who are a higher risk of recurrence (ROR) and may benefit from adjuvant chemotherapy
- Anticipated launch 2023

Primary Immunotherapy Response (PIR) Test

- Test for selecting treatment naïve NSCLC patients for immune checkpoint inhibitor regimens independent of, and complementary to PD-L1 status
- Anticipated launch 2023

Driving near-term & long-term value creation and ongoing revenue

Significant experience to date working with biopharma customers

50+ companies

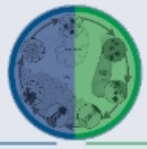
150,000+ sample & data biobank

Select publicly-disclosed biopharma customers

Genentech
Pfizer
AstraZeneca
MERCK
EMD SERONO
KYMERA
AVEO ONCOLOGY
CHECKMATE PHARMACEUTICALS
immodulon
HiberCell

Our suite of diagnostic testing solutions for biopharma customers

TUMOR PROFILING ◀ ▶ **HOST & IMMUNE PROFILING**



NGS (genomics)

- *GeneStrat NGS (52 genes)*
- Lung cfTNA Assay (12 genes)
- Lung cfDNA Assay (11 genes)
- Breast cfDNA Assay v2 (12 genes)
- Breast cfDNA Assay (10 genes)
- Colon cfDNA Assay (14 genes)
- Myeloid Assay (40 DNA genes + 29 fusions)
- Tumor Mutation Burden (TMB)
- Comprehensive Assay Plus (500+ genes, TMB, MSI)
- TCR Beta (long & short read) Assay
- Whole Exome Sequencing
- Methylome Sequencing
- Whole Transcriptome Sequencing

ddPCR™ (genomics)

- **GeneStrat® Test***
  (EGFR L858R, del19, UCV multiplex, T790M | ALK | ROS1 | RET | KRAS | BRAF)
- **SARS-CoV-2 ddPCR Test†**
- EGFR del19 multiplex*
- EGFR C797S*
- PD-L1 Expression
- Microsatellite Instability
- Custom Assays

LC-MS (proteomics)

- **Nodify XL2® Test***
- Lung Protein Panel (388 proteins)
- MRM Assays
- Unbiased DIA LC-MS
- Direct Neoantigen Characterization
- Custom Assays

ELISA (proteomics)

- **Nodify CDT™ Test***
- **Platelia SARS-CoV-2 Total Ab† Test**
- **cPass Neutralizing Ab test†**
- Custom Assays

MALDI (proteomics)

- **VeriStrat® Test***
- *Primary Immune Response*
- *Lung Cancer Risk of Recurrence*
- Biological Pathway Protein Score (PSEA)
- Antibody MALDI
- Custom Protein Signatures

PASEF timsToF (proteomics)

- Shotgun Proteomics
- Custom Assays

SEER Proteograph™

- Custom Research

AI Services	• AI – based algorithm: COVID-19 Risk of severe outcomes • Exact Shapley Value algorithmic research
Devices	• **Genomic & proteomic blood-stabilizing collection device**

*NYS-CLEP approved **Bolded** = commercially available *Italics* = diagnostics in commercial pipeline † FDA EUA Authorized

Accomplishments and Updates

PRODUCTS

- Continued **expansion of sales force** - doubling from 24 sales reps in 2020 to 48 in 2021
- Launched **cPass Neutralizing Antibody test** for COVID-19
- Announced launch of **new 52-gene NGS test** with unprecedented 72-hour turn around time
- Ordering Physicians, ordering Hospitals, and testing volumes increasing over 2020 and early 2021 tempered by surges in COVID-19 DELTA infections and weather with regional influence on recovery

PARTNERSHIPS

- Signed multiple new technology and diagnostic partnerships
  - **HiberCell** – Initiated broad collaboration for companion diagnostic discovery, development, and commercialization
  - **Datavant** – Tokenization of portion of data and sample biobank
  - **Seer** – Combining Seer platform technology with Diagnostic Cortex proprietary AI platform to dive deeper into the proteome

DATA and REGULATORY

- Biodesix lab in De Soto, KS received **ISO 13485:2016** certification and **CAP** accreditation
- Enrolling patients in four prospective studies: **ALTITUDE, BEACON Lung, ORACLE, and INSIGHT**

Our Leadership Team

Extensive knowledge in diagnostics & reimbursement

Scott Hutton
CEO

Spectranetics
Medtronic

Robin Harper Cowie
CFO

PrecisionTherapeutics
UPMC

Kieran O'Kane
CCO

nanoString

Gary Pestano
CDO (PhD)

Roche VENTANA
HARVARD MEDICAL SCHOOL

Bobbi Coffin
CGO

exact sciences
PrecisionTherapeutics
CYTEC

Ryan Siurek
CAO

VAIL RESORTS
Sprint lyondellbasell

Robert Georgantas
SVP Research (PhD)

abbvie
JOHNS HOPKINS UNIVERSITY

Steven Springmeyer
CMO (MD)

Indi
spiration

James Jett
CMO (MD)

Oncimmune
UPMC

Linda Traylor
VP CDMA (PhD)

NOVARTIS Duke
Abbott

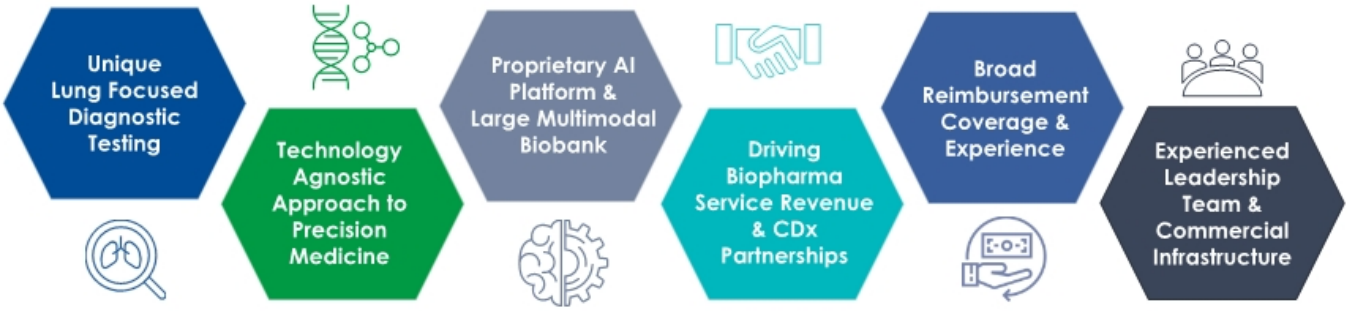
Paul Beresford
CBO (PhD)

Roche VENTANA
HARVARD MEDICAL SCHOOL

Brianna Phillips
Head Qual & Reg

Medtronic
COVIDIEN

We are a data-driven diagnostic solutions company



$29B+	7	27	300+	50+	450K+	150K+
total US market opportunity*	lung focused diagnostic tests	clinical studies	publications & presentations	biopharma customers	tests performed	sample & data biobank

*Figure includes the US lung cancer testing opportunity of $27B plus the $2B biopharma biomarker and CDx opportunity

biodesix®

Appendix

Appendix

A Board of Directors with a vast amount of industry expertise

John Patience CHAIRMAN	Crabtree Partners LLC	McKinsey &Company	
Scott Hutton PRESIDENT & CEO	biodesix	Spectranetics Always Reaching Farther	Medtronic
Hany Massarany COMPENSATION COMMITTEE	GenMark Dx	Roche	VENTANA
Jean Franchi AUDIT COMMITTEE	Replimune	MERRIMACK PHARMACEUTICALS	SANOFI GENZYME
Matt Strobeck NOMINATIONS & GOVERNANCE COMMITTEE	Birchview Capital	WESTFIELD CAPITAL MANAGEMENT	Metabolix
Jack Schuler	SCHULER SCHOLAR PROGRAM	Abbott	
Charles Watts, M.D.	Northwestern University	UNIVERSITY OF MICHIGAN	SWEDISH

We have **two** certified, high-complexity laboratories

biodesix lung REFLEX biodesix WorkSafe™ COVID-19 TESTING PROGRAM

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

nodify lung biodesix WorkSafe™ COVID-19 TESTING PROGRAM

- ✓ **CAP**-accredited
- ✓ **COLA**-accredited
- ✓ **NYS CLEP** certified: Soluble Tumor Markers & Diagnostic Immunology
- ✓ **ISO 13485**-certified
- ✓ **FDA** Emergency Use Authorization

Intellectual property portfolio

87 issued patents

50 in the US and 37 foreign;
17 U.S. and 25 foreign applications still in various stages of prosecution

25 unique & active registered trademarks

across 11 countries

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
- Pipeline tests using proteomic testing in immunotherapies
- Biodesix Blood Collection Device
- Proteomic drug-associated tests developed for our 3rd party partners

Exemplary Issued Trademarks:

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