

**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**

January 8, 2021

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.)

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 2.02. Results of Operations and Financial Condition.

On January 8, 2021, Biodesix, Inc. (the “Company”) issued a press release announcing certain of its preliminary estimates of unaudited financial results as of and for the three-month period ended December 31, 2020. A copy of the press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

The information contained in this Item 2.02 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 7.01. Regulation FD Disclosure.

On January 8, 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 99.2. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

The information contained in this Item 7.01 and Exhibit 99.2 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	Press Release issued by Biodesix, Inc. dated January 8, 2021
99.2	Corporate Presentation of Biodesix, Inc., dated January 8, 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: January 8, 2021

BIODESIX, INC.

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

Biodesix Anticipates Strong Preliminary Fourth Quarter 2020 Revenue (unaudited)

Record quarterly revenue driven by strength in COVID-19 testing and growth in lung diagnostic testing

Boulder, CO, January 8, 2021 - Biodesix, Inc. a leading data-driven diagnostic solutions company with a focus in lung disease, today announced that the company expects to report record fourth quarter 2020 preliminary unaudited revenue in a range of \$25 million to \$27 million. The strength in the fourth quarter 2020 was a result of growth in the company's COVID-19 testing services, lung diagnostic testing, and biopharma services. The financial results included in this release pertaining to all interim periods are unaudited and the financial results as of and for the three-month period ended December 31, 2020 are preliminary unaudited information and subject to final review and adjustments.

Fourth Quarter 2020 and Recent Highlights

- Generated record revenue of \$25 million to \$27 million for the three months ended December 31, 2020.
- Completed initial public offering (IPO) that raised net proceeds of approximately \$63 million after deducting offering costs, underwriting discounts and commissions, providing significant cash resources to fund the Company's growth strategy and for working capital and general corporate purposes.
- Initiated biomarker study to affirm Nodify XL2® test's importance in clinical decision making (ALTITUDE). The first-in-class biomarker study is aligned with the recommendations from the official 2018 American Thoracic Society (ATS) policy statement on the early detection of lung cancer. Dr. Gerard A. Silvestri of Medical University of South Carolina named Principal Investigator.
- Announced results of study showing the company's proprietary blood collection device (BCD) collects, separates, and transports blood at ambient temperature to simplify specimen collection and transport while maintaining accuracy of diagnostic test results.
- Partnered with Purdue University to support return to school COVID-19 testing for off campus students.

"We are pleased to see the growth in our lung diagnostic testing during the quarter even as healthcare practitioners and facilities were focused treating patients during the most recent surge of COVID-19 cases across the country," stated Scott Hutton, Chief Executive Officer. "With our diverse suite of commercially available lung cancer nodule management and tumor profiling tests, as well as the broad array of assays that we perform on behalf of our biopharmaceutical partners, we are very well positioned to continue to drive growth in our base business in 2021."

"The growth in our COVID-19 revenue reflects the value of our COVID-19 tests and our service capabilities to help a variety of customers across the country. While the country grapples with the uncertainty of the progression of the pandemic, we are pleased to offer the highly-accurate and rapid results that our customers require," Mr. Hutton concluded.

Revenue

We preliminarily estimate our revenues for the three months ended December 31, 2020 to be approximately \$25 million to \$27 million as compared to \$9.2 million for the three months ended September 30, 2020, an increase of 172% to 193%, and as compared to \$8.3 million for the three months ended December 31, 2019, an increase of 201% to 225%. Diagnostic test revenue and services revenue comprised an estimated 93% to 94% and 7% to 6% of estimated total revenues, respectively, for the three months ending December 31, 2020 as compared to 93% and 7%, respectively, for the three months ending September 30, 2020. Lung diagnostic testing revenue comprised approximately \$3.5 million to \$4.0 million for the three months ending December 31, 2020, as compared to \$3.0 million for the three months ending September 30, 2020, an increase of 17% to 33%, and compared to \$4.6 million for the three months ending December 31, 2019, a decrease of 13% to 24%, as health care practitioners, including pulmonologists, were diverted to pandemic-related care in 2020. COVID-19 testing services revenue comprised approximately \$20 million to \$21 million for the three months ending December 31, 2020, as compared to \$5.5 million for the three months ending September 30, 2020, an increase of 264% to 282%.

Liquidity

The Company continues to maintain a strong liquidity position, primarily as a result of our IPO generating net cash proceeds of approximately \$63 million, with cash and cash equivalents of approximately \$62 million as of December 31, 2020, which reflects a required pre-payment of approximately \$7 million for three years of premiums for the company's directors and officers (D&O) liability insurance coverage. We expect our current cash position to provide sufficient liquidity to meet our growth expectations, including our ability to meet our financial obligations for at least the next twelve months.

About Biodesix

Biodesix is a leading diagnostic company with a focus in lung disease. The company develops diagnostic tests addressing important clinical questions by combining multi-omics through the power of artificial intelligence. Biodesix is the first company to offer six non-invasive tests for patients with diseases of the lung. Biodesix launched the SARS-CoV-2 ddPCR™ test and the Platelia SARS-CoV-2 Total Ab in response to the global pandemic and virus that impacts the lung and causes COVID-19. The blood based Biodesix Lung Reflex® strategy for lung cancer patients integrates the GeneStrat® and VeriStrat® tests to support treatment decisions with results in 72 hours, expediting time to treatment. The blood based Nodify Lung™ nodule risk assessment testing strategy, consisting of the Nodify XL2® and the Nodify CDT™ tests, evaluates the risk of malignancy in incidental pulmonary nodules, enabling physicians to better triage patients to the most appropriate course of action. Biodesix also collaborates with many of the world's leading biotechnology and pharmaceutical companies to solve complex diagnostic challenges in lung disease. For more information about Biodesix, visit biodesix.com.

Note Regarding Forward-Looking Statements

This press release may contain forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical fact, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "plan,"

“expect,” “predict,” “potential,” “opportunity,” “goals,” or “should,” and similar expressions are intended to identify forward-looking statements. Such statements are based on management’s current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors. Biodesix has based these forward-looking statements largely on its current expectations and projections about future events and trends. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. Forward-looking statements may include information concerning the impact of the COVID-19 pandemic on Biodesix and its operations, it’s possible or assumed future results of operations, including descriptions of its revenues, profitability, outlook and overall business strategy. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results to differ materially from those contemplated in this press release can be found in the Risk Factors section of Biodesix’s public filings with the Securities and Exchange Commission, including Biodesix’s final prospectus filed on October 29, 2020 under Rule 424(b)(4) in connection with the company’s initial public offering. Biodesix undertakes no obligation to revise or publicly release the results of any revision to such forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

Contacts:

Media:

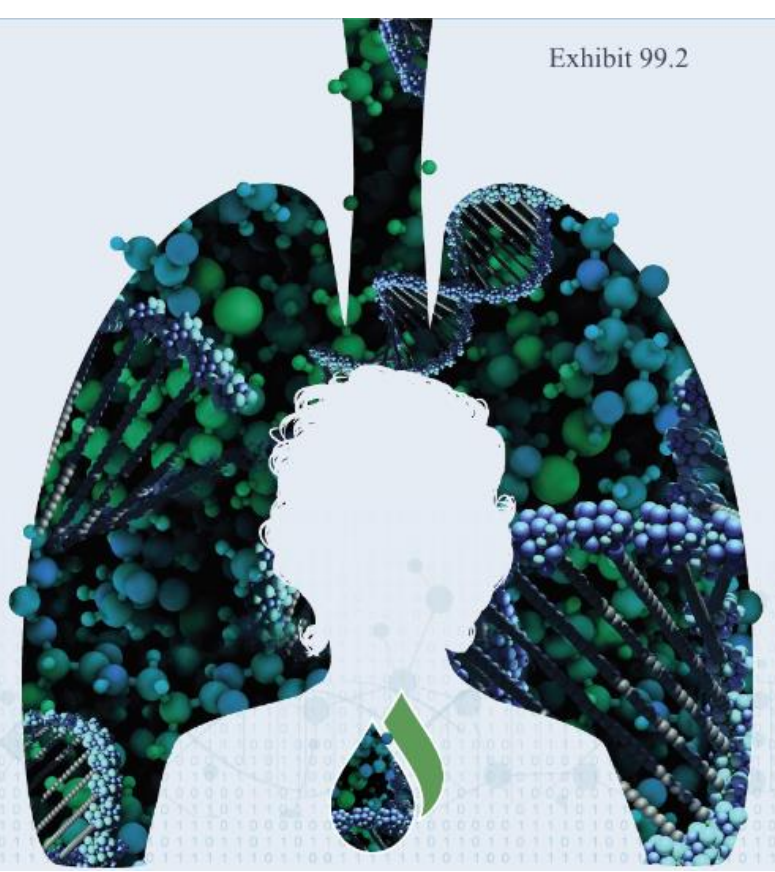
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 **biodesix**[®]
Corporate Presentation

JANUARY 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



Robin Harper Cowie
Chief Financial Officer

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

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



Chief Operating Officer



SVP & General Manager of the Vascular Intervention division



VP & General Manager of Neurosurgery
VP & Business Leader of Surgical Navigation and Intra-Operative Imaging



VP of Finance
VP of Reimbursement & Health Economics
Senior Director and Director of Reimbursement
Director of Payor & Government Relations
Manager of Business Development Planning & Analysis

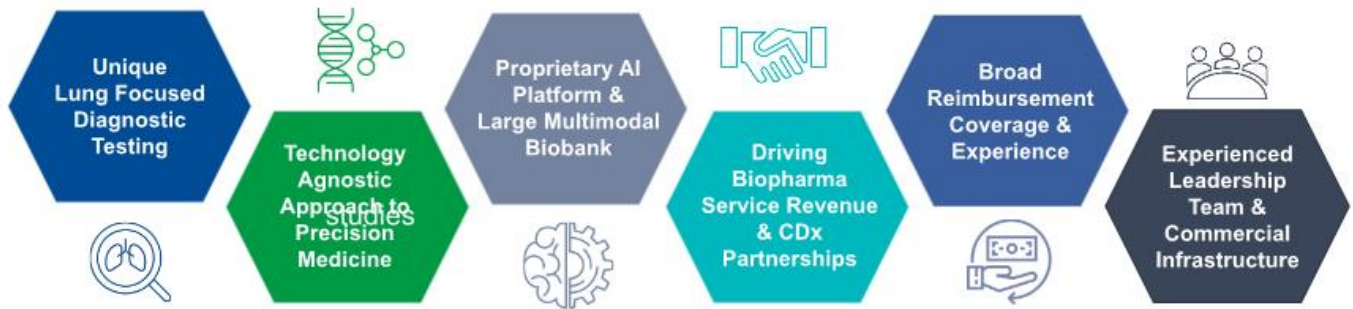


Former Laboratory Manager, Researcher



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.

We are a data-driven diagnostic solutions company



\$29B+

total US market opportunity*

6

lung focused diagnostic tests

27

clinical studies

275+

publications & presentations

50+

biopharma customers

245K+

tests performed

140K+

sample & data biobank

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

© 2021 Biodesix, Inc. All rights reserved.

We have 6 diagnostic tests for lung disease



*Commercialized in partnership with Bio-Rad Laboratories
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\$27B+ annual U.S. lung cancer testing market opportunity

#1 deadliest cancer with more deaths annually than the next three deadliest cancers combined (colorectal, pancreas, and breast)



How can we improve the risk assessment of suspicious lung nodules?

5M+ lung nodules discovered eligible for risk assessment testing

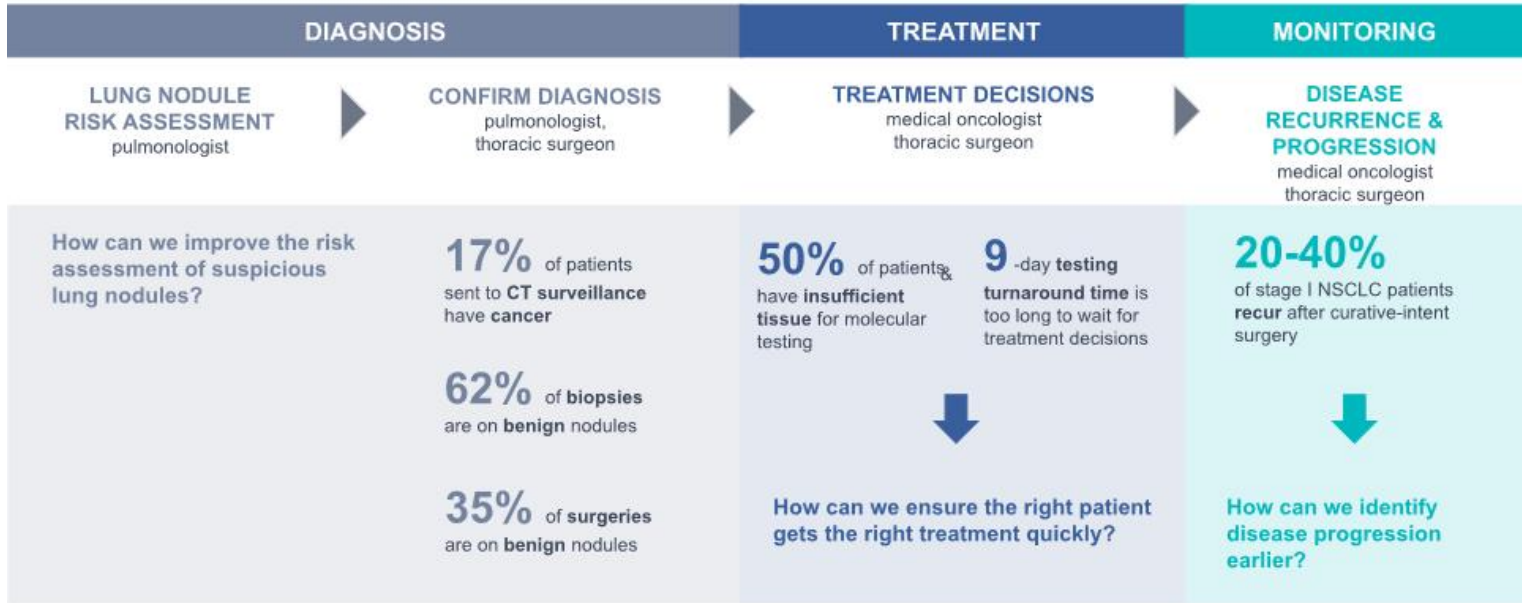
How can we ensure the right patient gets the right treatment quickly?

4M+ molecular testing opportunities to guide treatment decisions

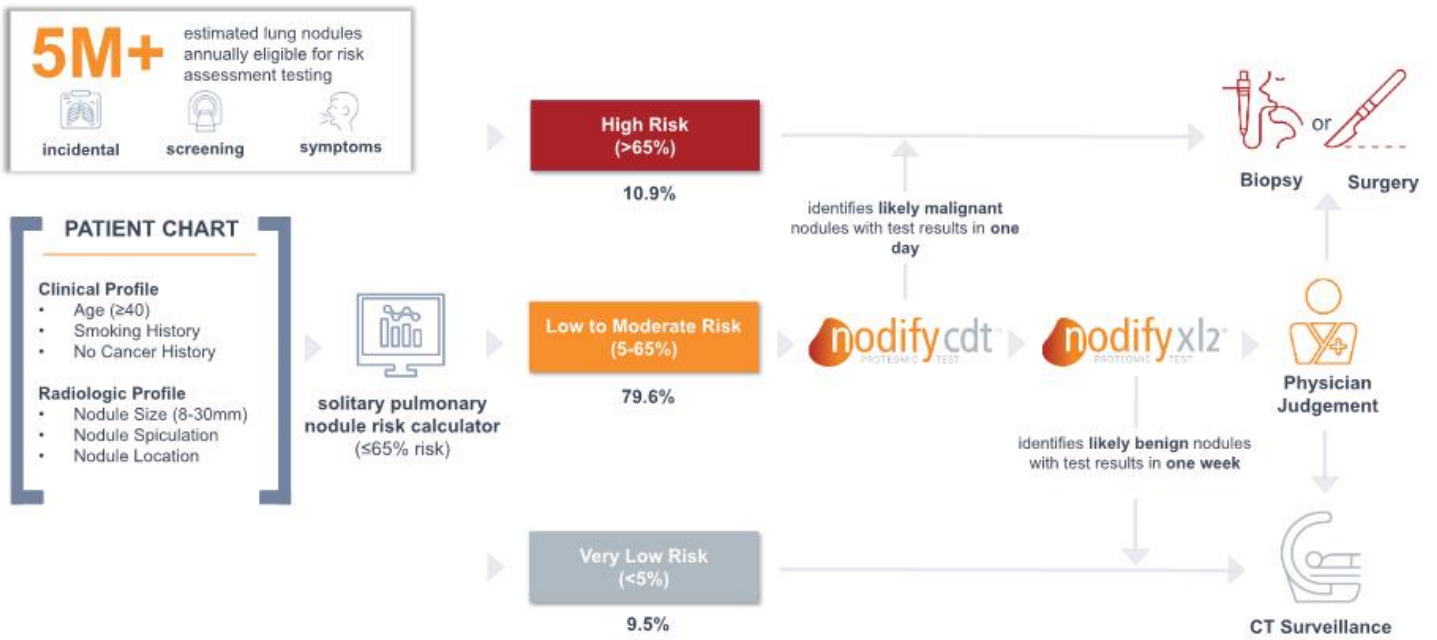
How can we identify disease progression earlier?

800K+ treatment monitoring testing opportunities

Identifying clinical unmet needs in patient care



Understanding lung nodule management





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



98% specificity, 28% sensitivity & 78% PPV



1-day turnaround time



Full commercial launch **March 2020**



Beginning efforts with payers



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



97% sensitivity, 44% specificity & 98% NPV



4 to 5-day turnaround time



Full commercial launch **October 2019**



Medicare coverage with a unique CPT code & ADLT status (\$3,520)

Two studies ongoing (ORACLE & ALTITUDE) for combined lung nodule risk assessment and combined 26 peer-reviewed publications & presentations combined.

We are committed to advancing our clinical data package

ALTITUDE Clinical Utility Study



- First-in-class biomarker study for the early detection of lung cancer
- Multicenter, randomized controlled, prospective clinical utility study
- Initiated December 2020
- Principal Investigator is Dr. Gerard Silvestri
- 2,000 patient enrollment goal
- Interim results expected 2022

<https://clinicaltrials.gov/ct2/show/NCT04171492>

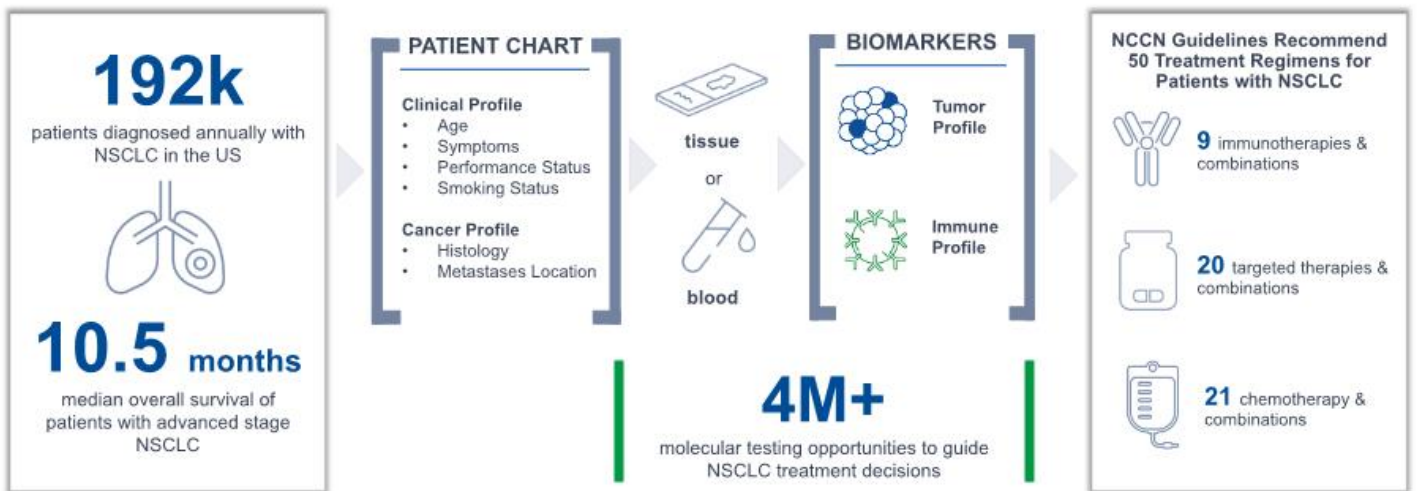
ORACLE Registry Study



- Observational registry study
- Designed to evaluate the clinical utility of the Nodify XL2 test
- Initiated October 2018
- Principal Investigator is Dr. Michael Pritchett
- 423 patients have been enrolled and are undergoing primary endpoint analysis
- 2-year follow-up anticipated in 2022

<https://clinicaltrials.gov/ct2/show/NCT03766958>

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



genestrat
genomic test

veristrat
proteomic test



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



Mutations detected by ddPCR from blood
DNA: EGFR | BRAF | KRAS
RNA: EML4-ALK | ROS-1 | RET



91% sensitivity & 100% specificity



3-day turnaround time



Medicare and private payer coverage
Not restricted by stage of NSCLC or multiple tests per patient per cancer



30+ publications & presentations



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



3-day turnaround time



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



85+ publications & presentations

Greater than 3,500+ patients enrolled in INSIGHT¹ registry study

Informing initial treatment decisions with **quick, actionable results**



We **complement NGS testing** by giving the physician a quick look at actionable mutation results to inform **initial treatment decisions** regarding **FDA-approved targeted therapies and immunotherapies**.



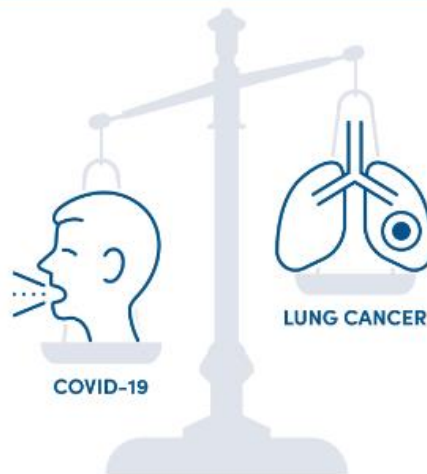
Our **response** to the COVID-19 pandemic

They asked, we responded.

We are a trusted partner to our pulmonology customers through their fight on the front-line with COVID-19 patients, meanwhile continuing to drive informed diagnostic and treatment decisions for patients with lung cancer.

biodesix WorkSafe™
COVID-19 TESTING PROGRAM

supporting the pandemic with
COVID-19 testing



modifylung™
NODULE RISK ASSESSMENT

helps **prioritize patients** for
diagnostic intervention with
suspicious lung nodules

biodesix lung™
REFLEX

helps **inform treatment options**
and **timing** following a new lung
cancer diagnosis

**Bio-Rad SARS-CoV-2
ddPCR Test**



Detects active infection
identifies who should quarantine & self-isolate



Molecular test detected by ddPCR
SARS-CoV-2 N gene (N1 & N2) | human Rpp30 gene
Self-collect mid-nasal swab



100% concordance with CDC assay
in symptomatic individuals



1 to 2-day turnaround time



Full commercial launch **April 2020**

**Bio-Rad Platelia SARS-CoV-2
Total Ab Test**



Detects previous infection
identifies who may have previously been exposed or infected



Serology test detected by ELISA
Antibodies to SARS-CoV-2: IgG | IgM | IgA
Blood draw



98% sensitivity & 99% specificity
>8 days post onset of symptoms



1 to 2-day turnaround time



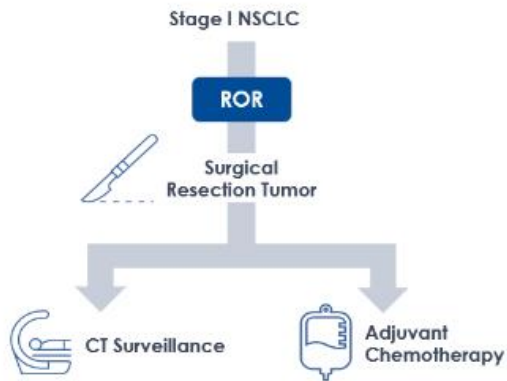
Full commercial launch **June 2020**

Both tests are issued an Emergency Use Authorization by the FDA

We are committed to answering critical clinical questions in lung cancer

Risk of Recurrence (ROR) Test

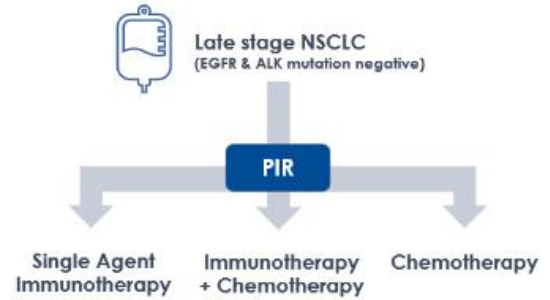
We discovered a host immune profiling signature that can help identify **stage 1 NSCLC** patients' **pre-surgery** who are at a **higher risk of recurrence** and may benefit from **adjuvant chemotherapy**.



Primary Immune Response (PIR) Test

We discovered a host immune profiling signature that provides clinically meaningful information for selecting **treatment naïve NSCLC** patients for **immunotherapy regimens independent of**, and complementary to PD-L1 expression status.

Prospective clinical validation study (BEACON-Lung¹) recently announced with ALCMI.



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

Significant experience to date working with biopharma customers



50+ companies



140,000+
sample & data biobank

Select publicly-disclosed biopharma customers

MERCK



AstraZeneca



Genentech

**EMD
SERONO**

KYMERA

CHECKMATE
PHARMACEUTICALS

immodulon

Our 2020 accomplishments

On October 28, 2020, Biodesix began trading on the Nasdaq Global Market, under the symbol "BDSX".

PRODUCTS & SERVICES

- ✓ Nodify CDT test launch
- ✓ Biodesix WorkSafe
 - ✓ ddPCR test launch
 - ✓ Ab test launch
- ✓ Biodesix Blood Collection Device (BCD)

COLLABORATIONS

- ✓ Streck
- ✓ Merck KGaA & Pfizer
- ✓ Bio-Rad
- ✓ ALCMI
- ✓ Colorado State University
- ✓ Big Ten Conference
- ✓ State of Colorado
- ✓ Purdue University

DATA & STUDIES

- ✓ 25+ peer-reviewed publications & posters
- ✓ 7 issued patents
- ✓ Announced the BEACON-Lung observational study
- ✓ Initiated the ALTITUDE clinical study

Our 2020 performance & long-term growth plan

(\$, in millions)



*These are not projections; they are goals and are forward-looking, subject to significant business, economic, regulatory and competitive uncertainties and contingencies, many of which are beyond the control of Bodesix and its management, and are based upon assumptions with respect to future decisions, which are subject to change. Actual results will vary, and those variations may be material. Nothing in this presentation should be regarded as a representation by any person that these goals will be achieved and Bodesix undertakes no duty to update its goals. See page 2 of this presentation for factors that may impact our long term plan and our objectives for year over year growth set out above. Financial results estimates for the fourth quarter of 2020 are preliminary and subject to change as we complete our quarter closing procedures.

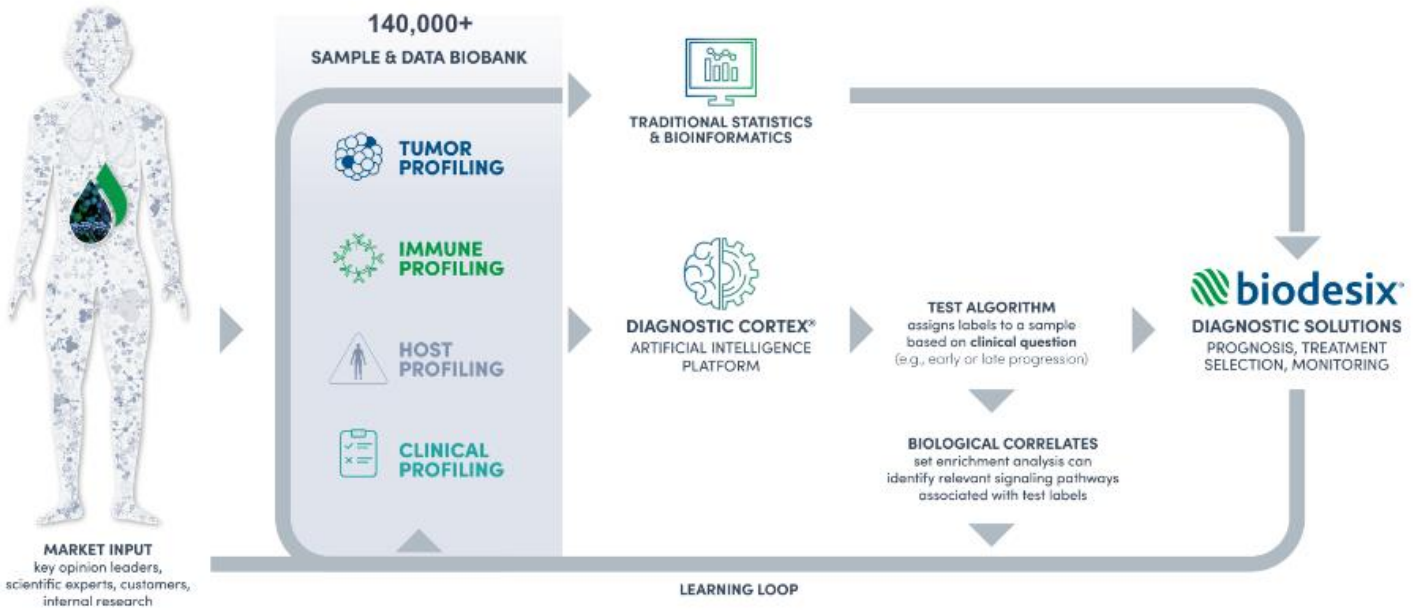
 **biodesix**[®]
Appendix



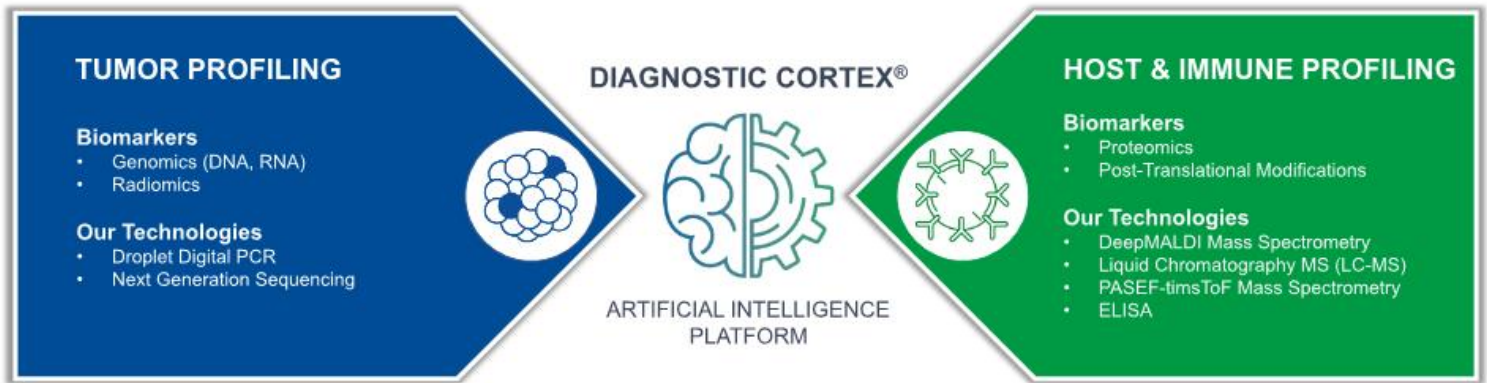
We derive our revenue from **two sources**



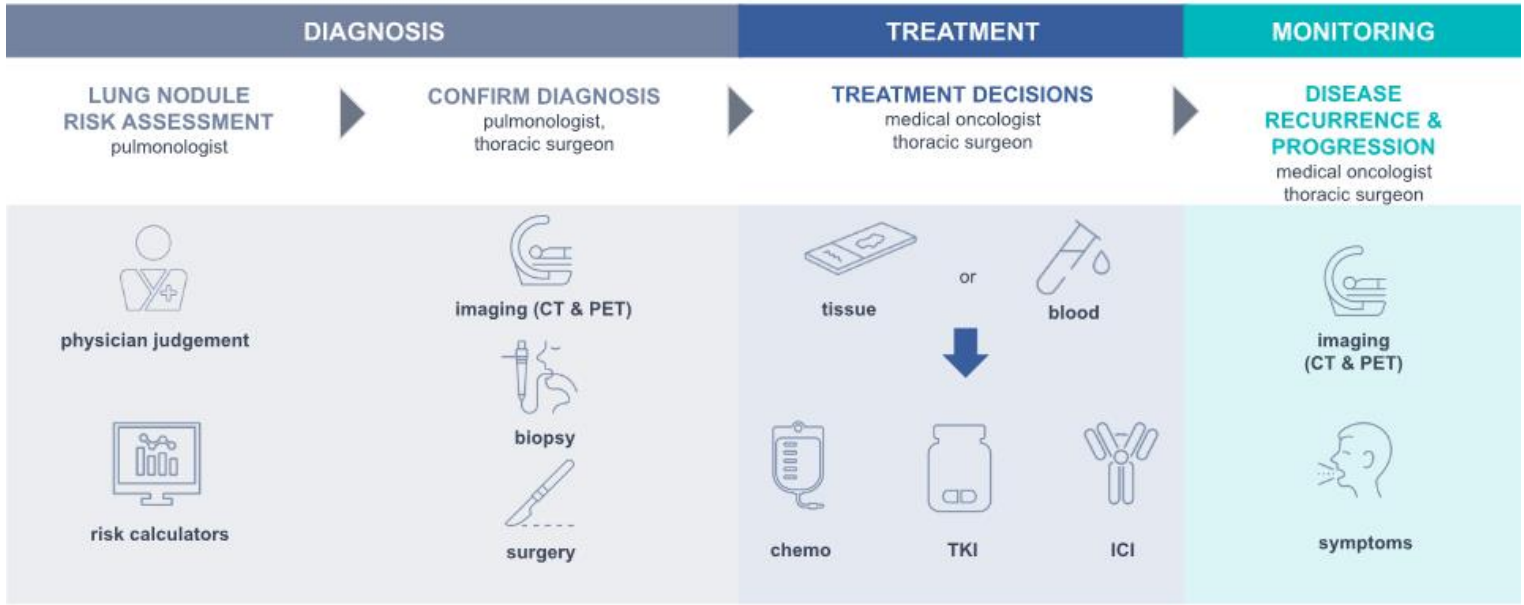
Unique in our approach to precision medicine



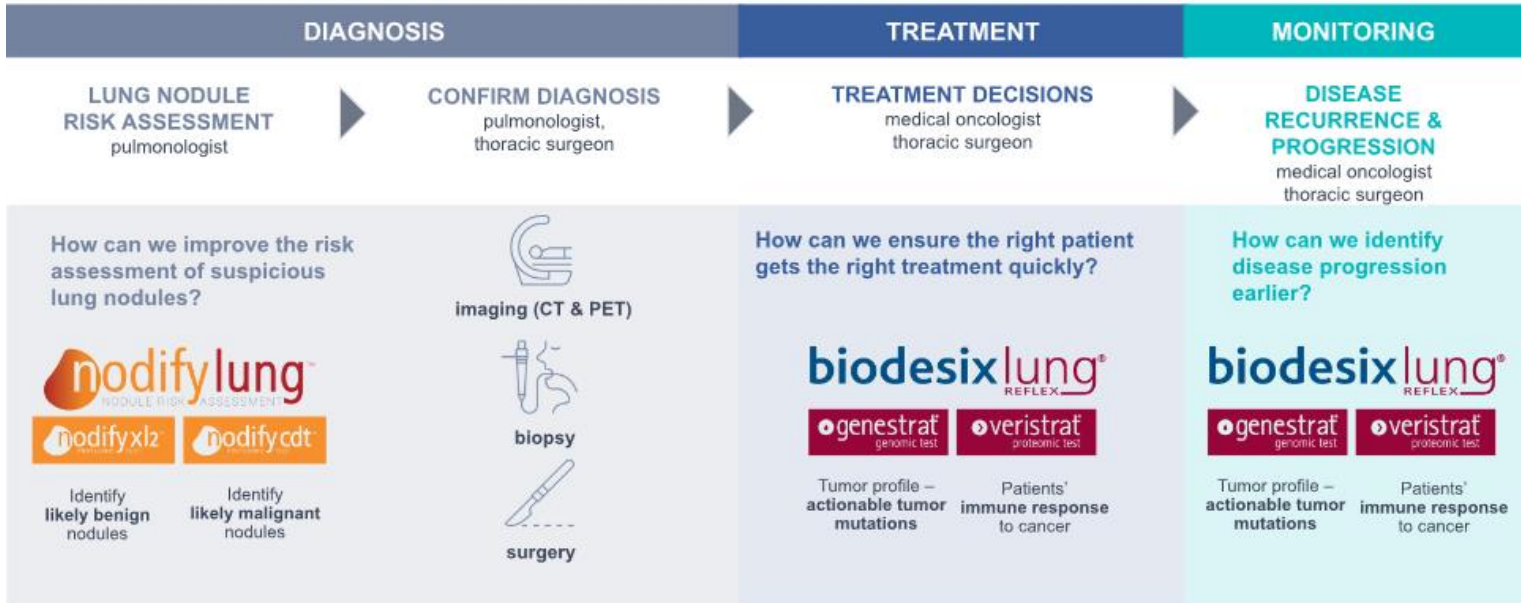
Uncovering the depth and breadth of disease biology from **blood**



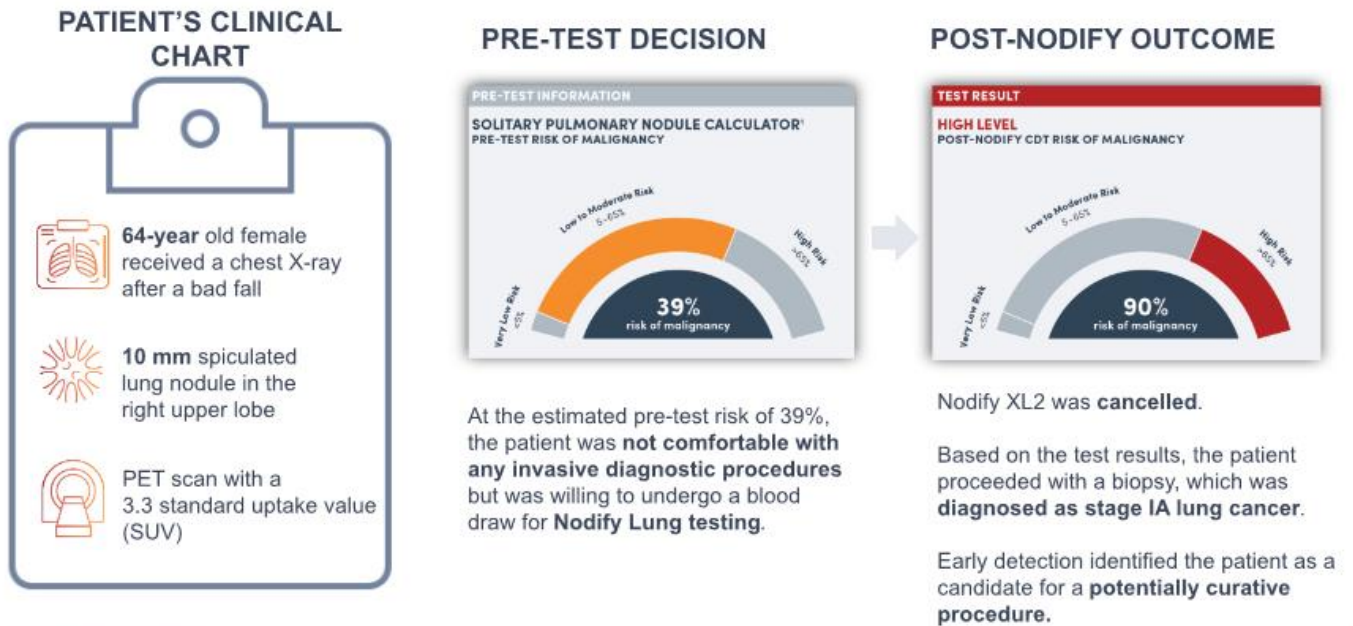
Understanding standard of care



Our portfolio of 4 blood-based diagnostic tests

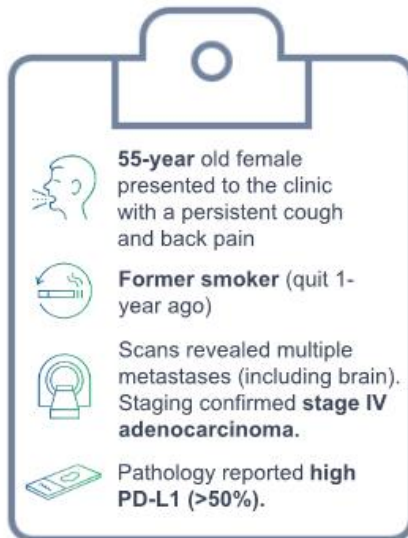


Case Study: Catching curable cancer with faster intervention



Case Study: Changing lung cancer patient's treatment plan

PATIENT'S CLINICAL CHART



55-year old female presented to the clinic with a persistent cough and back pain

Former smoker (quit 1-year ago)

Scans revealed multiple metastases (including brain). Staging confirmed **stage IV adenocarcinoma**.

Pathology reported **high PD-L1 (>50%)**.

TREATMENT PLANNING

The physician advised the patient of her potential eligibility for **single agent immunotherapy (based on a high PD-L1 status & less treatment side effects)** but wanted to order molecular testing. Immunotherapy is more harmful in patients with either EGFR or ALK driver mutations. **Biodesix Lung Reflex was ordered for a quick look for driver mutations & assessment of immune disease state.**

genestrat
genomic test

MUTATION NEGATIVE
[EGFR | EML4-ALK | ROS-1 | RET | BRAF | KRAS]

veristrat
proteomic test

VERISTRAT POOR
[aggressive disease state]

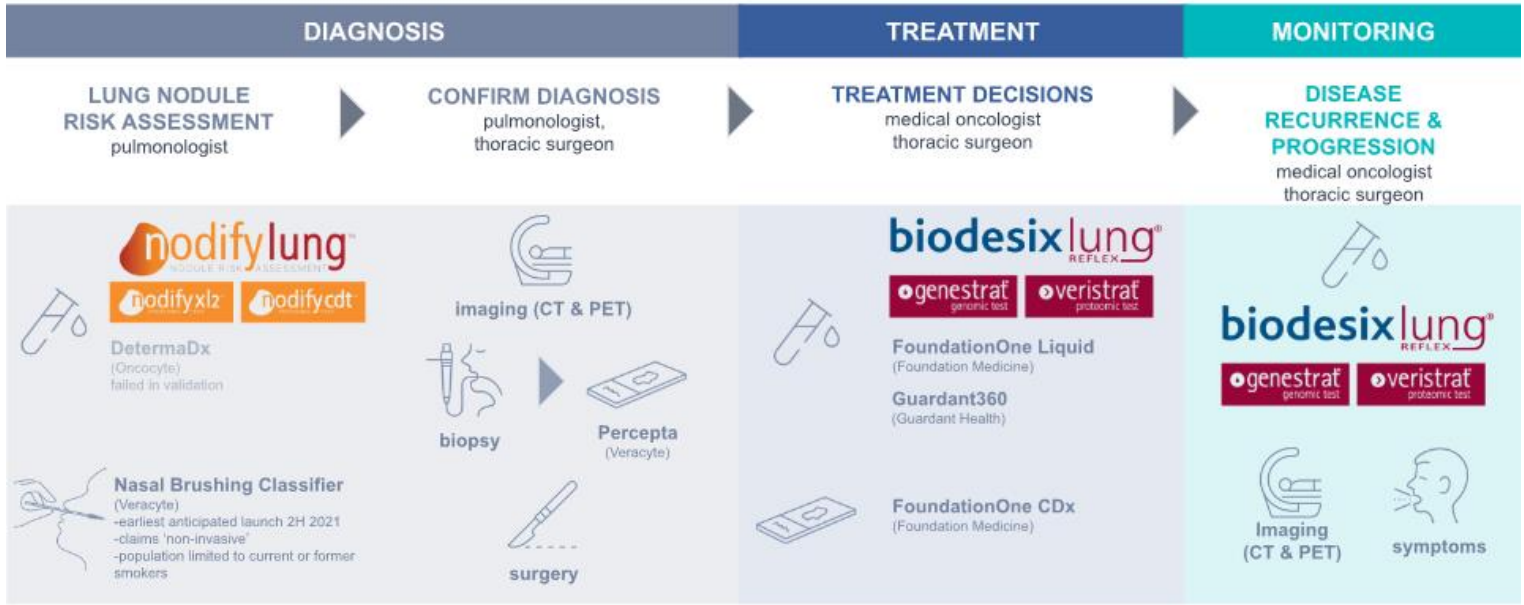
Results

- **Immunotherapy is an option** for the patient due to the GeneStrat mutation negative results
- VeriStrat Poor identified the **need to expedite time to treatment** and be **more aggressive with a treatment regimen**

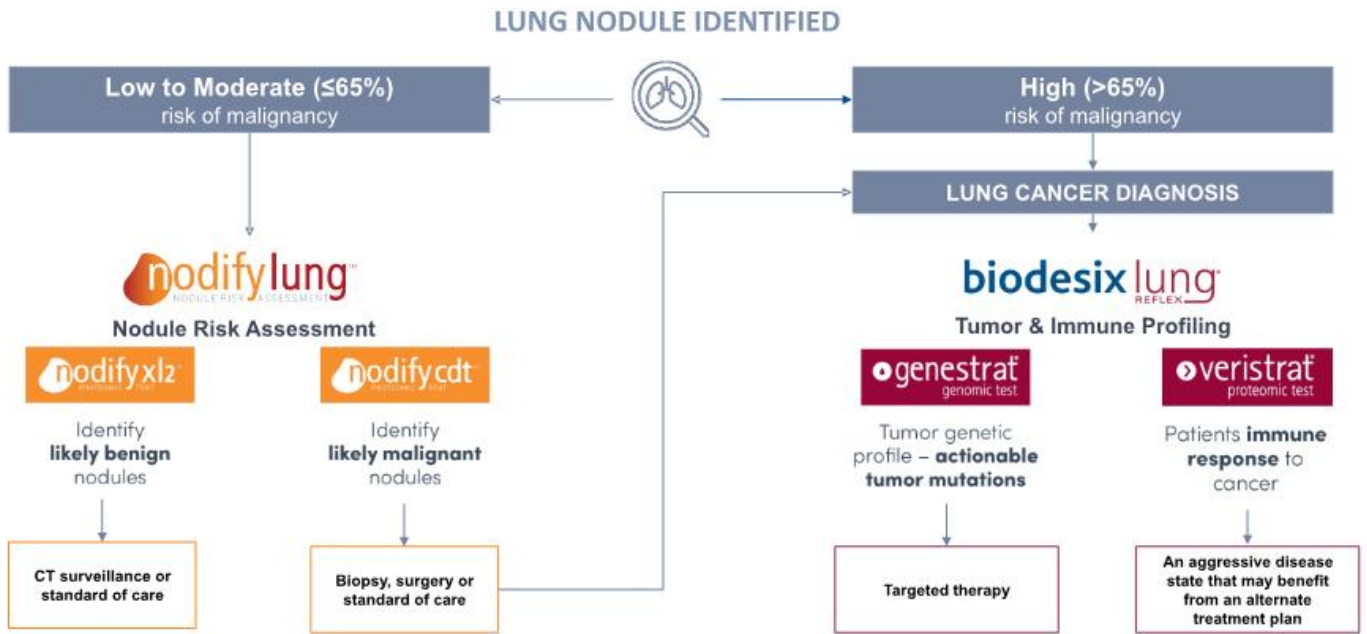
Outcome

- The patient began treatment with a **combination immunotherapy and chemotherapy regimen**
- Patient has been **alive for over 18 months**

Where our peer-products fit along the patient treatment pathway



Our testing strategies fit together in a simple portfolio



We employ a multifaceted strategy to drive Nodify Lung adoption



KOL DEVELOPMENT & PARTNERSHIPS | CLINICAL STUDIES | GUIDELINES INCLUSION | BROAD REIMBURSEMENT

Our lung-focused sales force distributed across the U.S.

2020 year-end

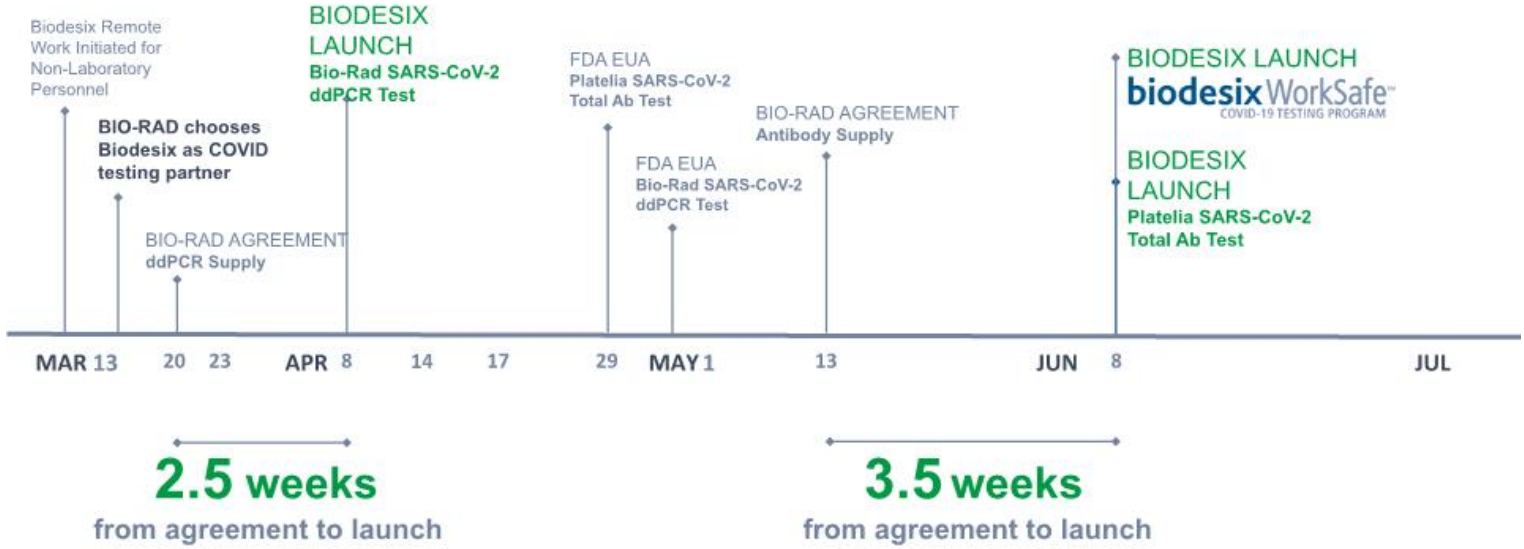


2022 year-end*



*Represents our objectives for 2022 based on current plans. Actual sales force distribution across geographies in the United States may differ as we reassess our plans.

Our team, capabilities and partnerships enable our speed and agility



\$2B+ annual biopharma biomarker testing & CDx market opportunity

The use of biomarker testing in clinical trials has increased from:

15% in 2000¹ ▶ **55%** in 2018¹

Biomarker-driven drug development leads to a 570% increase in drug approval success rates



1. LEK and PMC 2019. The evolution of biomarker use in clinical trials for cancer treatments. 2. Wong CH et al. Biostatistics, Volume 20, Issue 2, April 2019, Pages 273-286
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We provide end-to-end diagnostic solutions for biopharma customers

Discovery

- Data-driven Diagnostic Solutions
- Technology Agnostic Approach
- Proprietary AI Platform
- Tumor & Host/Immune Profiling
- Multi-Omic & Single-Omic
- Biomarker Discovery & Feasibility



**TUMOR
PROFILING**



**HOST & IMMUNE
PROFILING**

Development

- Two Highly-Certified Clinical Laboratories
- Established Product Development Process
- Proven Success at Rapid Diagnostic Development
- Quality & Regulatory Excellence

- ✓ CAP-accredited
- ✓ CLIA & COLA-certified
- ✓ NYS CLEP certified
- ✓ ISO 13485-certified
- ✓ FDA Emergency Use Authorizations

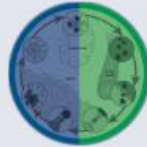
Commercialization

- Successfully Commercialized 6 Diagnostic Tests for Clinical Use
- Experts in Reimbursement
- National Field-Based Sales & Medical Affairs Team
- In-House Billing & Customer Care



Our suite of diagnostic testing solutions for biopharma customers

**TUMOR
PROFILING**



**HOST & IMMUNE
PROFILING**

NGS

- GeneStrat 52 pan-Cancer cf Assay
- Lung cfDNA 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)
- Whole Exome Sequencing
- Methylome Sequencing
- Whole Transcriptome Sequencing

ddPCR™

- **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

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

NGS

- TCR Beta (long & short read) Assay
- Immune Expression Assay
- Whole Transcriptome Sequencing

MALDI

- **VeriStrat® Test**
- ImmunoStrat® Suite of Protein Signatures
- Lung Cancer Risk of Recurrence Signature
- Biological Pathway Protein Score (PSEA)
- Antibody MALDI
- Custom Protein Signature Discovery

ELISA

- **Nodify CDT™ Test**
- **Platelia SARS-CoV-2 Total Ab Test**

*NYS-CLEP approved **Bolded** = commercial clinical diagnostic tests

ORACLE Registry Study (NCT03766958)



Title: ORACLE - An Observational Registry Study to Evaluate the Performance of the Nodify XL2 Test.

Status: The first patient enrolled on October 16, 2018. As of May 1, 2020, 423 patients have been enrolled and are undergoing primary endpoint analysis, with 2-year follow-up estimated to be completed by the first half of 2022.

Study Rationale: Designed to develop real-world clinical utility data for Nodify XL2.

Primary Objective: To show a reduction in invasive procedures on patients with benign nodules compared to a historical control group obtained from chart review.

ALTITUDE Clinical Utility Study (NCT04171492)



Title: ALTITUDE - Multicenter, Randomized Controlled Trial, Prospectively Evaluating the Clinical Utility of the Nodify XL2 Proteomic Test in Incidentally Discovered Low to Moderate Risk Lung Nodules.

Status: Received central investigational review board (IRB) approval in December 2019 and have an enrollment goal of 2,000 patients. First patient first visit was in December 2020.

Study Rationale: Designed to evaluate the performance of Nodify Lung (Nodify XL2 and Nodify CDT) in a randomized controlled study (RCT).

Objectives & Design: To evaluate how the addition of the Nodify Lung test result impacts the clinical decision making for patients with new, incidentally identified solid lung nodules assessed as low to moderate risk of lung cancer. The trial has an adaptive study design with a blinded standard of care arm and 2:1 randomization for open-label results for Nodify XL2.

- Phase 1 of the study with only Nodify XL2 is expected to enroll 500 patients.
- Phase 2 of the adaptive study design will include an open-label arm for Nodify CDT, which is aligned with our commercial testing algorithm.

INSIGHT Observational Study (NCT03289780)



Title: An Observational Study Assessing the Clinical Effectiveness of VeriStrat and Validating Immunotherapy Tests in Subjects with Non-Small Cell Lung Cancer (INSIGHT)

Status: The first patient enrolled was on May 11, 2016. To date, we have over 3,500 patients enrolled with a target 5,000 enrollment goal. Final analysis with 3-year follow-up is estimated to be completed by 2024. Results of an interim analysis were presented at ASCO 2020.

Study Rationale: Designed to evaluate the real-world clinical utility and performance of the Biodesix Lung Reflex (GeneStrat and VeriStrat) testing strategy.

Objectives: To guide the adoption of VeriStrat and inform medical decision making, including treatment choice, and enable the validation of additional mass spectrometry-based proteomic tests. To describe the impact of the VeriStrat test results on treatment decisions, including but not limited to the percentage change in treatment decision, differences in chosen treatments between patients classified as VeriStrat Good and those classified as VeriStrat Poor, and the percentage of patients receiving systemic therapy or supportive therapies only.

Beacon-Lung Clinical Study (NCT04676386)

Primary Immune Response Test

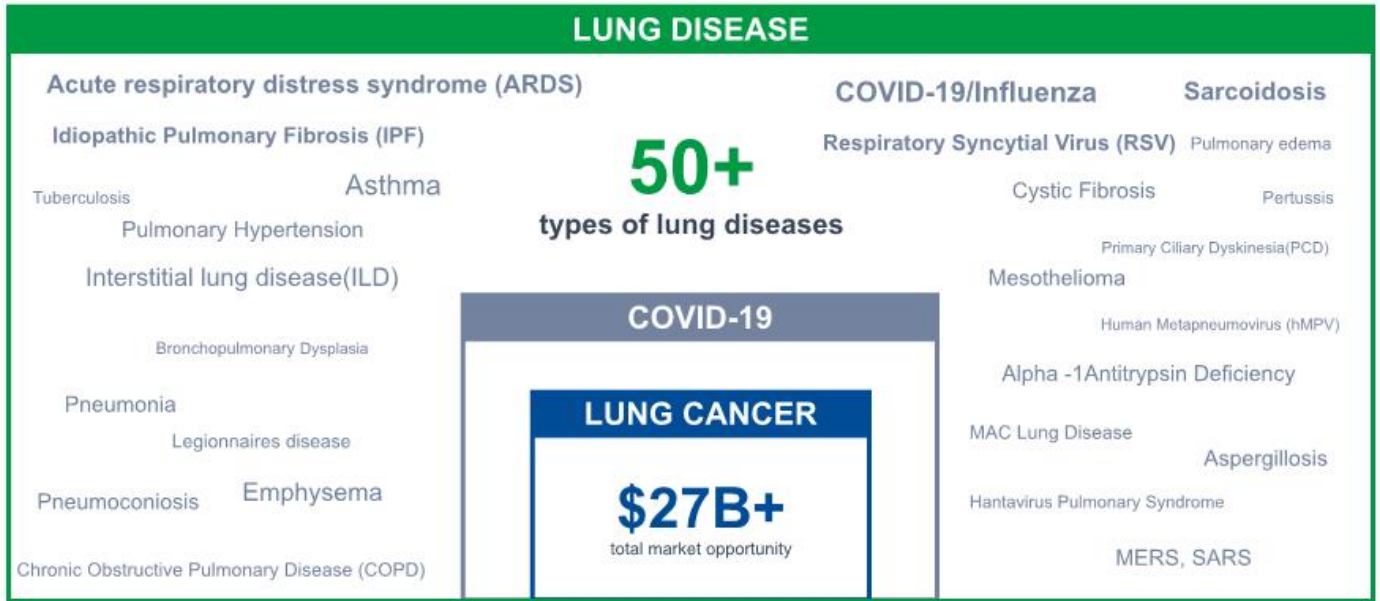
Title: A Biomarker Analysis in High PD-L1 Expressing NSCLC Patients Treated With An Immune Checkpoint Inhibitor (ICI) With or Without Platinum-Based Chemotherapy

Status: This study will be carried out in collaboration with the Addario Lung Cancer Medical Institute (ALCMI) team. The IRB was submitted December 2020.

Study Design: An observational, multicenter, open-label study to assess biomarkers (serum, microbiome, radiomics and tissue) as predictive of early progression in 390 treatment-naive patients with advanced stage NSCLC and PD-L1 greater than or equal to 50% treated with two standard of care regimens, triplet therapy (platinum-based chemotherapy plus ICI regimen) and ICI monotherapy (single agent ICI).

Study Objective: To collect biospecimens and evaluate candidate biomarkers, with a focus on PIR, to detect early progression on ICI monotherapy versus triplet therapy.

Significant growth potential as we expand into lung disease



Biodesix WorkSafe Testing Partnerships & Testimonials

[Purdue partners with Colorado company to offer rapid testing for students ahead of spring 2021 semester](#)
January 6, 2021

[Big Ten Conference Partners with Biodesix, Inc. and Quidel Corporation](#)
September 30, 2020

[Biodesix to Provide COVID-19 Testing for Colorado State University Campus](#)
August 12, 2020

[Major League Lacrosse Partners with Biodesix](#)
July 13, 2020

[Biodesix Partners with Boulder Community Health to Expand Access to COVID-19 Testing](#)
May 20, 2020



"Biodesix helped Carroll College organize and test more than 1,000 students on campus for COVID-19 over a one-week period. The Biodesix team was well organized, they responded to our questions promptly, and the turnaround time for testing results was as described. We are very satisfied with their work!" – Jennifer at Carroll College

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



biodesix lung **biodesix WorkSafe**
REFL.CX 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



nodifylung **biodesix WorkSafe**
COVID-19 TESTING PROGRAM

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

We combined the Seattle, WA and De Soto, KS laboratories

Pre-analytic specimen collection solutions

We have enabled ambient shipping ('no cold chain') with specimen preservation for our diagnostic tests



Our patented Biodesix Blood Collection Device (BCD)

US Patent No. 10,422,729



Whole Blood Transport & Plasma Separation Device

- Combines multiple sample processing steps, including specimen collection and reproducible sample separation with ambient shipping.
- Specimen detection has been demonstrated with analytic measures of proteins and gene targets using highly sensitive mass spectrometry, PCR and NGS methods.
- We are exploring options to monetize the patented device in genomics and proteomics applications.

Intellectual property portfolio



84 issued patents

49 in the US and 35 foreign;
16 U.S. and 23 foreign applications still in various stages of prosecution

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



33 registered trademark numbers

across 12 countries

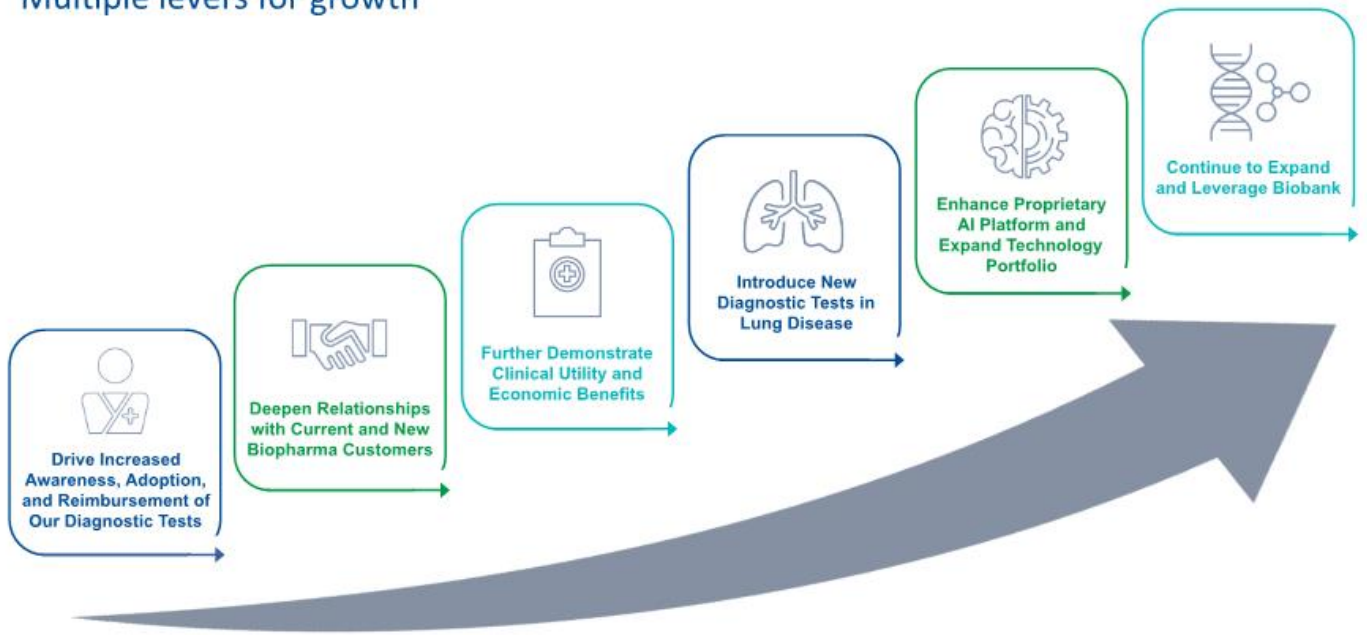
Exemplary Issued Trademarks:

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

Filed not yet issued:

- Nodify CDT
- Nodify Lung

Multiple levers for growth



Extensive knowledge in diagnostics & reimbursement



Spectranetics
Medtronic



PrecisionTherapeutics
UPMC



nanoString
Roche



Roche VENTANA
HARVARD MEDICAL SCHOOL



abbvie
JOHNS HOPKINS UNIVERSITY



EMCO
PrecisionTherapeutics
CYTIC



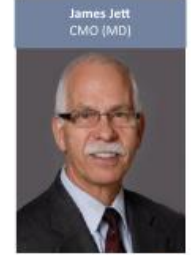
Roche VENTANA
HARVARD MEDICAL SCHOOL



NOVARTIS Duke
Abbott



















Indi
spiration



Oncimmune
UPMC

A Board of Directors with a vast amount of industry expertise

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 **biodesix**[®]

