## **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

Date of Report (Date of earliest event reported): May 5, 2023

### **FULGENT GENETICS, INC.**

(Exact Name of Registrant as Specified in Charter)

Delaware (State or other jurisdiction of incorporation)

81-2621304 001-37894 (Commission File Number)

(IRS Employer Identification No.)

4399 Santa Anita Avenue El Monte, California (Address of Principal Executive Offices)

91731 (Zip Code)

(626) 350-0537 (Registrant's telephone number, including area code)

Chec	k the appropriate box below if the Form 8-K filing is inte	nded to simultaneously satisfy the filing obligation of	f the registrant under any of the following provisions:							
	Written communications 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 communications pursuant to Rule	14d-2(b) under the Exchange Act (17 CFR 240.14d-2	2(b))							
	Pre-commencement communications pursuant to Rule	13e-4(c) under the Exchange Act (17 CFR 240.13e-4	(c))							
Secu	rities 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 \$0.0001 per share	FLGT	The Nasdaq Stock Market (Nasdaq Global Market)							
the S	ecurities Exchange Act of 1934 (§240.12b-2 of this chapt		ties Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of							
Eme	rging growth company □									
	emerging growth company, indicate by check mark if the unting standards provided pursuant to Section 13(a) of the	e	on period for complying with any new or revised financial							

#### Item 2.02 Results of Operations and Financial Condition.

On May 5, 2023, Fulgent Genetics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended March 31, 2023. A copy of the Company's press release containing this information is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

#### Item 7.01 Regulation FD Disclosure.

From time to time, the Company presents and/or distributes slides and presentations to the investment community to provide updates and summaries of its business. On May 5, 2023, the Company updated its investor presentation, which is available on the "Investor Relations" section of the Company's website at https://fulgentgenetics.com/. This presentation is also furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in Items 2.02 and 7.01, including Exhibits 99.1 and 99.2, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
No.	··· <b>f</b> ··
99.1	Press Release of Fulgent Genetics, Inc., dated May 5, 2023
99.2	Corporate Presentation of Fulgent Genetics, Inc.
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.

Date: May 5, 2023 FULGENT GENETICS, INC.

By: /s/Paul Kim

Name: Paul Kim

Title: Chief Financial Officer

#### Fulgent Reports First Quarter 2023 Financial Results

- Total Revenue of \$66.2 million
- Record Core Revenue of \$62.7 million, growth of 150% year-over-year
- Raises Full Year 2023 Core Revenue Guidance to \$250 million

EL MONTE, CA, May 5, 2023 — Fulgent Genetics, Inc. (NASDAQ: FLGT) ("Fulgent" or the "Company"), a technology-based company with a well-established clinical diagnostic business and a therapeutic development business, today announced financial results for its first quarter ended March 31, 2023.

#### First Quarter 2023 Results:

- Total Revenue of \$66.2 million
- Core Revenue<sup>1</sup> grew 150% year-over-year to \$62.7 million
- GAAP loss of \$15.3 million, or \$0.52 per share
- Non-GAAP loss of \$6.5 million, or \$0.22 per share
- Adjusted EBITDA loss of \$7.2 million
- Cash, cash equivalents, and investments in marketable securities, excluding investment pending cash settlement, of \$867.8 million as of March 31, 2023

#### Note:

1) Core Revenue excludes revenue from COVID-19 testing products and services including COVID-19 NGS testing revenue.

Non-GAAP income (loss), non-GAAP income (loss) per share, and adjusted EBITDA income (loss) are described below under "Note Regarding Non-GAAP Financial Measures" and are reconciled to the most directly comparable GAAP financial measure, GAAP income (loss), in the accompanying tables.

Commenting on the results, Ming Hsieh, Chairman of the Board and Chief Executive Officer, said, "We are off to a strong start in 2023, with strength in our core genetics business across our three main areas -- precision diagnostics, anatomic pathology, and pharma services. We are encouraged by the early interest in our expanded carrier screening through Beacon787. In our therapeutics business, we look forward to sharing Phase 1b data next month at the American Society of Clinical Oncology annual meeting for our lead drug candidate, FID-007, in various cancers, and furthering this clinical program."

Paul Kim, Chief Financial Officer, added, "We are raising our guidance for the year due to our outperformance in the first quarter. While we are still not guiding to COVID-19 revenue, we are pleased with our results in the core business and continue to see financial strength. Our cash position continues to afford us the flexibility to be opportunistic and strategic in building a sustainable business for the long-term."

#### Outlook:

For the second quarter of 2023, Fulgent expects:

Core Revenue of approximately \$62 million

For the full year 2023, Fulgent now expects:

- Core Revenue of approximately \$250 million
- GAAP loss of approximately \$2.50 per share

Non-GAAP loss of approximately \$1.25 per share

#### Conference Call Information

Fulgent will host a conference call for the investment community today at 8:30 AM ET (5:30 AM PT) to discuss its first quarter 2023 results. The call may be accessed through a live audio webcast in the Investor Relations section of the Company's website, http://ir.fulgentgenetics.com. An audio replay will be available at the same location.

#### Note Regarding Non-GAAP Financial Measures

Certain information set forth in this press release, including non-GAAP income (loss), non-GAAP income (loss) per share, and adjusted EBITDA income (loss) are non-GAAP financial measures. Fulgent believes this information is useful to investors because it provides a basis for measuring the performance of the Company's business, excluding certain income or expense items that management believes are not directly attributable to the Company's operating results. Fulgent defines non-GAAP income (loss) as net income (loss) calculated in accordance with accounting principles generally accepted in the United States of America, or GAAP, plus amortization of intangible assets, plus restructuring costs, plus acquisition-related costs, including banking fees and legal fees associated with acquisitions, plus equity-based compensation expense, plus or minus other charges or gains, as identified, that management believes are not representative of the Company's operations. The non-GAAP tax effect is calculated by applying the statutory corporate tax rate on the amortization of intangible assets, restructuring costs, acquisition-related costs, and equity-based compensation expense. Fulgent defines adjusted EBITDA income (loss) as GAAP income (loss) plus or minus interest (expense) income, plus or minus provisions (benefits) for income taxes, plus restructuring costs, plus acquisition-related costs, plus equity-based compensation expense, plus depreciation and amortization, and plus or minus other charges or gains, as identified, that management believes are not representative of the Company's operations. Fulgent may continue to incur expenses similar to the items added to or subtracted from GAAP financial measures should not be construed as an implication that these items are unusual, infrequent or non-recurring. Management uses these non-GAAP financial measures should not be considered in isolation from, or as a substitute for, financial information presented in conformity with GAAP, and non-GAAP financial measures as reported

#### **About Fulgent**

Fulgent is a technology-based company with a well-established clinical diagnostic business and a therapeutic development business. Fulgent's clinical diagnostic business offers molecular diagnostic testing services, comprehensive genetic testing, and high-quality anatomic pathology laboratory services designed to provide physicians and patients with clinically actionable diagnostic information to improve the quality of patient care. Fulgent's therapeutic development business is focused on developing drug candidates for treating a broad range of cancers using a novel nanoencapsulation and targeted therapy platform designed to improve the therapeutic window and pharmacokinetic profile of new and existing cancer drugs. The Company aims to transform from a genomic diagnostic business into a fully integrated precision medicine company.

#### Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of forward-looking statements in this press release include statements about, among other things: future performance; guidance regarding expected quarterly and annual financial results, core revenues, GAAP loss, and non-GAAP loss; evaluations and judgments regarding the stability of certain revenue sources, momentum, vision, future opportunities and future growth the Company's testing services and technologies and expansion; the Company's identification and evaluation of opportunities and its ability to capitalize on opportunities, capture market share, or expand its presence in certain markets; and the Company's ability to continue to grow its business.

Forward-looking statements are statements other than historical facts and relate to future events or circumstances or the Company's future performance, and they are based on management's current assumptions, expectations, and beliefs concerning future developments and their potential effect on the Company's business. These forward-looking statements are subject to a number of risks and uncertainties, which may cause the forward-looking events and circumstances described in this press release to not occur, and actual results to differ materially and adversely from those described in or implied by the forward-looking statements. These risks and uncertainties include, among others: the market potential for, and the rate and degree of market adoption of, the Company's tests, including its Beacon787 panel; its ability to maintain turnaround times and otherwise keep pace with rapidly changing technology; the Company's ability to maintain the low internal costs of its business model; the Company's ability to maintain an acceptable margin; risks related to volatility in the Company's results, which can fluctuate significantly from period to period; risks associated with the composition of the Company's customer base, which can fluctuate from period and can be comprised of a small number of customers that account for a significant portion of the Company's revenue; the Company's level of success in obtaining coverage and adequate reimbursement and collectability levels from third-party payors for its tests and testing services; the Company's level of success in establishing and obtaining the intended benefits from partnerships, strategic investments, joint ventures, acquisitions, or other relationships; the success of the Company's development efforts, including the Company's ability to progress its candidates through clinical trials on the timelines expected; the Company's compliance with the various evolving and complex laws and regulations applicable to its business and its industry; and the Company's ability to prote

The forward-looking statements made in this press release speak only as of the date of this press release, and the Company assumes no obligation to update publicly any such forward-looking statements to reflect actual results or to changes in expectations, except as otherwise required by law.

The Company's reports filed with the U.S. Securities and Exchange Commission, or the SEC, including its annual report on Form 10-K for the year ended December 31, 2022, filed with the SEC on February 28, 2023, and the other reports it files from time to time, including subsequently filed annual, quarterly and current reports, are made available on the Company's website upon their filing with the SEC. These reports contain more information about the Company, its business and the risks affecting its business, as well as its results of operations for the periods covered by the financial results included in this press release.

#### **Investor Relations Contact:**

The Blueshirt Group Melanie Solomon, melanie@blueshirtgroup.com

## FULGENT GENETICS, INC.

Condensed Consolidated Balance Sheet Data March 31, 2023 and December 31, 2022 (in thousands)

	 March 31, 2023		December 31, 2022	
ASSETS:				
Cash and cash equivalents	\$ 66,172	\$	79,506	
Investments in marketable securities	805,146		773,377	
Accounts receivable, net	43,549		52,749	
Property, plant, and equipment, net	79,083		81,353	
Other assets	382,817		399,068	
Total assets	\$ 1,376,767	\$	1,386,053	
LIABILITIES & EQUITY:				
Accounts payable, accrued liabilities and other liabilities	\$ 107,848	\$	116,178	
Total stockholders' equity	1,268,919		1,269,875	
Total liabilities & equity	\$ 1,376,767	\$	1,386,053	

#### FULGENT GENETICS, INC.

Condensed Consolidated Statement of Operations Data Three Months Ended March 31, 2023 and 2022 (in thousands, except per share data) (unaudited)

	Three Months Ended March 31,					
		2023		2022		
Revenue	\$	66,168	\$	320,268		
Cost of revenue (1)		47,357		77,725		
Gross profit		18,811		242,543		
Operating expenses:						
Research and development (1)		9,782		5,989		
Selling and marketing (1)		10,083		7,940		
General and administrative (1)		21,802		25,775		
Amortization of intangible assets		1,968		906		
Total operating expenses		43,635		40,610		
Operating (loss) income		(24,824)		201,933		
Interest and other income, net		3,775		45		
(Loss) income before income taxes		(21,049)		201,978		
(Benefit from) provision for income taxes		(5,200)		48,421		
Net (loss) income from consolidated operations		(15,849)		153,557		
Net loss attributable to noncontrolling interests		509		422		
Net (loss) income attributable to Fulgent	\$	(15,340)	\$	153,979		
Net (loss) income per common share attributable to Fulgent:						
Basic	\$	(0.52)	\$	5.09		
Diluted	\$	(0.52)	\$	4.93		
Weighted average common shares:						
Basic		29,536		30,234		
Diluted		29,536		31,240		
(1) Equity based componentian symmetry was allegated as follows:						
(1) Equity-based compensation expense was allocated as follows:  Cost of revenue	\$	2 204	¢	1.465		
Research and development	\$	2,394	\$	1,465 1,921		
Selling and marketing		3,448 1,361		825		
General and administrative						
	\$	3,062	¢	1,405		
Total equity-based compensation expense	<b>3</b>	10,265	\$	5,616		

#### FULGENT GENETICS, INC.

Non-GAAP Income (Loss) Reconciliation Three Months Ended March 31, 2023 and 2022 (in thousands, except per share data)

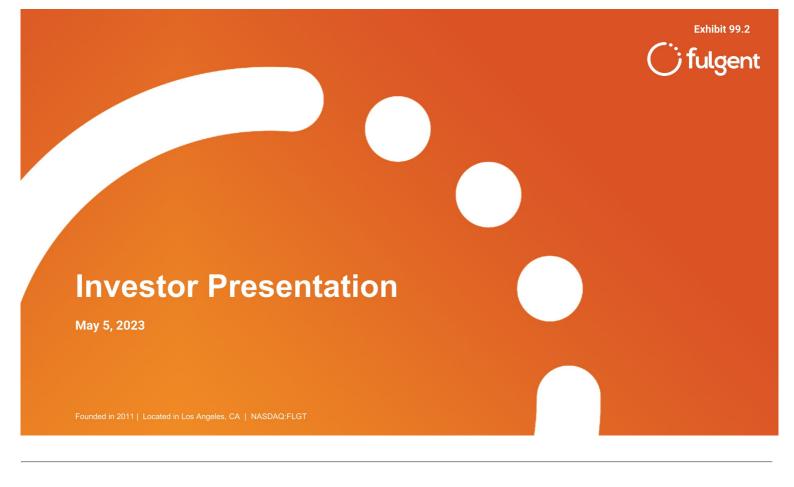
Three Months Ended March 31,			
-	2023	2022	
\$	(15,340)	\$	153,979
	1,968		906
	10,265		5,616
	(3,425)		(1,826)
\$	(6,532)	\$	158,675
\$	(0.52)	\$	5.09
\$	(0.52)	\$	4.93
\$	(0.22)	\$	5.25
\$	(0.22)	\$	5.08
	29,536		30,234
	29,536		31,240
	\$ \$ \$	\$ (15,340) 1,968 10,265 (3,425) \$ (6,532) \$ (0.52) \$ (0.52) \$ (0.22) \$ (0.22)	\$\begin{align*} \begin{align*} \begi

<sup>(1)</sup> Tax rates as follows:

Corporate tax rate of 28% for the three months ended March 31, 2023 and March 31, 2022.

#### FULGENT GENETICS, INC. Non-GAAP Adjusted EBITDA Reconciliation Three Months Ended March 31, 2023 and 2022 (in thousands)

		Three Months Ended March 31,					
	202	3		2022			
Net (loss) income attributable to Fulgent	\$	(15,340)	\$	153,979			
Interest (income) expense, net		(3,772)		739			
(Benefit from) provision for income taxes		(5,200)		48,421			
Equity-based compensation expense		10,265		5,616			
Depreciation and amortization		6,879		4,695			
Adjusted EBITDA	\$	(7,168)	\$	213,450			



## Disclaimer

#### Forward-Looking Statements and Market Data

This presentation contains forward-looking statements, which are statements other than those of historical facts and which represent the estimates and expectations of Fulgent Genetics, Inc. (the "Company") about future events based on current views and assumptions. Examples of forward-looking statements made in this presentation include, among others, those related to long-term upside or value, management of risk, anticipated growth and positioning, addressable market estimates, the Company's mission, vision and strategies, the success of its business model and strategy, anticipated future revenue and guidance, evaluations and judgments regarding the Company's business, products, technologies, competitive landscape, scalability, plans regarding development and launch of potential future products, and any businesses the Company may seek to acquire or has acquired or has invested in or may seek to invest in, including statements regarding Fulgent Pharma Holdings, Inc. ("Fulgent Pharma"), Inform Diagnostics, CSI Laboratories, Helio Health, Spatial Genomics, and any potential synergies, or transformation of the Company's business, long-term visions and strategies, including, with respect to Fulgent Pharma, those designated to create a vertically integrated solution for cancer care, the clinical development of Fulgent Pharma's pipeline and related statements and assumptions regarding development timeline any potentially accelerated pathway for regulatory approval, the potential safety and efficacy of the nanodrug delivery platform and any related therapeutic candidates, the potential market size for these candidates and platforms and the value of available data, including genomic data and guidance regarding the Company's future performance and results of operations. The Company's views and assumptions on which these forward-looking statements are based may prove to be incorrect. As a result, matters discussed in any forwardlooking statements are subject to risks, uncertainties and changes in circumstances that may cause actual results to differ materially from those discussed or implied by any forwardlooking statements. Important factors that could cause actual results to differ materially from those implied by forward-looking statements are disclosed under "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's reports filed with the Securities and Exchange Commission ("SEC"), including its annual report on Form 10-K filed on February 28, 2023, and other reports it files from time to time. Because of these factors, you should not rely upon forward-looking statements as predictions of future events. The forward-looking statements in this presentation are made only as of the date hereof, and, except as required by law, the Company assumes no obligation to update any forward-looking statements in the future. The company's reports filed with the SEC, including its annual report on Form 10-K for the year ended December 31, 2022, filed with the SEC on February 28, 2023, and the other reports it files from time to time, including subsequently filed quarterly and current reports, are made available on the company's website upon their filing with the SEC. These reports contain more information about the company, its business and the risks affecting its business, as well as its results of operations for the periods covered by the financial results included in this presentation.

This presentation also includes market data and forecasts with respect to the industry in which the Company operates. In some cases, the Company relies upon and refers to market data and certain industry forecasts that have been obtained from third-party surveys, market research, consultant surveys, publicly available information and industry publications that the Company believes to be reliable. These data and estimates involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

#### Non-GAAP Financial Measures

This presentation contains certain supplemental financial measures that are not calculated pursuant to U.S. generally accepted accounting principles ("GAAP"). These non-GAAP measures are in addition to, not a substitute for or superior to, measures of financial performance prepared in accordance with GAAP. A reconciliation of non-GAAP measures to GAAP measures is contained in this presentation



## Leadership Team



Ming Hsieh Chief Executive Officer

Experienced operational leader, entrepreneur and philanthropist

Previously CEO, President, and Chairman of Cogent Systems

Member of the National Academy of Engineering; Fellow of the National Academy of Inventors; Trustee of USC





**Paul Kim** Chief Financial Officer

Experienced financial leader and Certified Public Accountant

Previously CFO of Cogent Systems; sold to 3M for \$943M in 2010

B.A. in Economics from University of California at Berkeley

COGENT



Dr. Harry Gao Lab Director and Chief Scientific Officer

Previously Lab Director at City of Hope

Clinical molecular genetics training fellowship and post-doctoral fellowship at Harvard Medical School

M.S. in Immunology, and M.D. and Ph.D. in Microbiology, Immunology, and Medical Genetics

Cityof Hope



James Xie **Chief Operating** Officer

Responsible for managing all global operations, product vision and product engineering

Served as an SVP of Cogent

B.A. in Engineering, M.S. in Industrial Engineering and an M.S. in Computer Science

COGENT



**Brandon Perthuis** Chief Commercial Officer

Extensive experience leading genetic testing commercialization programs since 2003

Previously VP of Sales and Marketing of the Medical Genetics Laboratory at Baylor College of Medicine

Prior to Baylor, held senior roles at PerkinElmer and Spectral Genomics













**Dr. Lawrence Weiss** Chief Medical Officer

Esteemed background in molecular science and pathology

Most recently Chief Medical Officer at NeoGenomics; prior senior role at Clarient.

Chairman Emeritus of

Pathology at City of Hope National Medical Center







Dr. Ray Yin

President, Pharma

Founder & CEO, ANP

Former Team Leader of

Nanobiotechnology for Chem/Bio Defense, U.S. Army Research Laboratory

Technologies, Inc.









# **About Fulgent**

We are a premier global, technology-based genetic testing company focused on transforming patient care in oncology, infectious and rare diseases, and reproductive health.



## **Mission**

Develop flexible and affordable diagnostics and therapeutics that improve the everyday lives of those around us.

## **Core Values**

- Innovation
- Customer Service and Commitment
- Quality and Efficiency
- Our People

# **Strategy**

- Leverage our proprietary technology platform for broad application
- Further clinical/regulatory program for Pharma
- Operational excellence
- Disciplined M&A

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## Strategic Vision – A One-Stop Solution for Cancer Care



To build a vertically integrated solution to combat cancer early detection | clinical diagnostics | post treatment monitoring | drug discovery and cancer treatment





#### **FULGENT PHARMA**

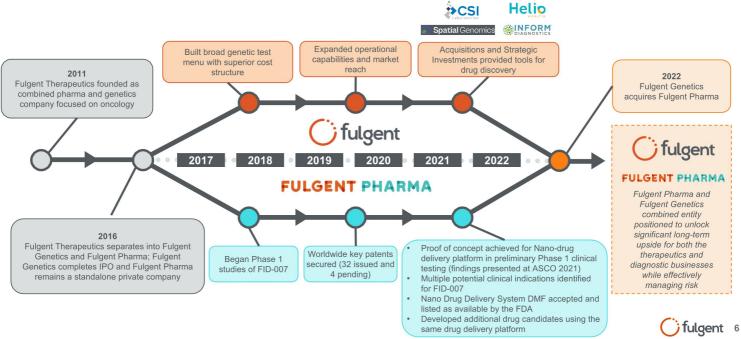
Leading Genetic Testing Company Offering Tech-Enabled Diagnostic Solutions

Nano-Drug Delivery Platform Exciting Cancer Therapeutic Opportunity Realizing Precision Medicine Potential

#### Therapeutic and Diagnostic Entity Providing Comprehensive Solutions Across the Cancer Care Continuum

- Vertically integrated "one-stop" solution across the healthcare chain following the CSI, Inform Diagnostics, and Pharma acquisitions
- Proprietary nano drug delivery technology platform serves as an underpinning technology between diagnostic and pharm to help create a more sustainable and profitable business model in precision medicine for years to come
- Addition of a talented scientific team creates a strong synergy and competitive advantage that may be leveraged across the combined
- Potential near-term opportunity includes shortened 505(b)(2) drug development and commercialization timelines and potential long-term opportunity leverages large data insights and novel analytical tools from diagnostics business to enable additional precision medicine pipeline through organic or partnered development strategies
- Commitment to continue growing diagnostic and therapeutic opportunities through organic investments and M&A
- Seasoned management team along with strong cash position allow Fulgent to enter therapeutic opportunities while managing risk





# Long-Term Vision: Fulgent Continuum of Care





- Transforms from a service company to a combined diagnostic and therapeutic company focused on precision medicine
- Large oncology market opportunity
- Careful pipeline management will responsibly engage therapeutic opportunities while managing potential
- Valuable, diverse assets and future sustainable revenue and margins



#### **FULGENT PHARMA**

- Well-funded by diagnostics to advance H&N therapy trials and commercialization process
- Genomics data accelerates pipeline therapeutics development, e.g. spatial biology for tumor microenvironment profiling
- Long-term opportunity to leverage data insights from diagnostics to enable precision medicine through proprietary or partnered development strategies
- Manufacturing capability to aid drug development



# DIAGNOSTICS



+150%

**Q1** YoY Core Revenue Increase

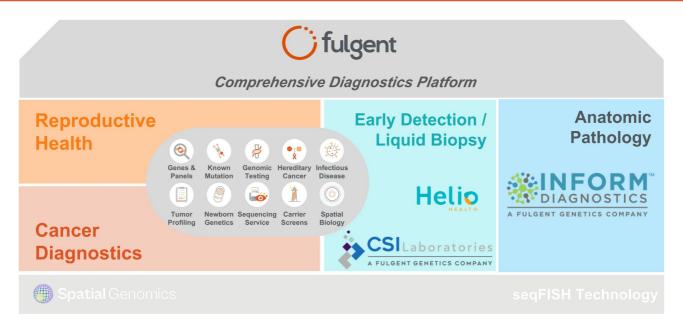
18,400+ GENES | 900+ PANELS **CUSTOMIZABLE OFFERINGS** 

## **Positioned for Growth**

- Proprietary technology platform allows for rapid scaling of a 1 broad, flexible test menu
- Next-generation sequencing (NGS) platform 2 complemented with growing portfolio of emerging testing technologies with a focus on oncology
- Well-positioned to execute on a growth strategy that includes 3 organic and inorganic initiatives, including:
  - Transformational acquisition of Inform Diagnostics
    - Ramping of CSI Labs
    - Scaling partnerships Helio Genomics and Spatial Genomics
    - Potential future acquisitions with a strategy of short- and longterm ROI, tangible synergies, and efficient capital deployment



# **Building Diagnostics Platform and Capabilities**





# **Target Market Opportunity**



**Cancer Diagnostics** 

\$80B market<sup>1</sup>

Early Detection / Liquid Biopsy

\$18B market<sup>1</sup>

Reproductive Health
\$8B market<sup>2</sup>

Pharma Services
\$50B market<sup>3</sup>

Market sizes sourced from Wall Street equity research
Market size sourced from Frost & Sullivan, October 2022
Market size sourced from Research and Markets, April 20



## **What Sets Fulgent Diagnostics Apart?**

#### Leads to a Broader Test Menu

- 18,400+ single-gene tests <sup>(1)</sup>
- 900+ panels
- Whole Genome and Exome
- Flexibility enables custom tests for any genes or conditions
- Preset panels have grown 350% since IPO in 2016

#### **And a Better Cost Structure**

- Lab efficiencies, automation and scale have translated to a sustainable cost structure
- Partnerships create leverage with sales and marketing
- Process 100% of volume without the need for outsourcing



**Superior Cost Structure** 

**Extensive Test Menu** 

**Technology Platform** 

1) Represents genes covered by single-gene tests.

A New Approach to NGS

Comparison and suppression algorithms Comprehensive analytics

Proprietary probes and engineered chemistry

powered by AI and ML



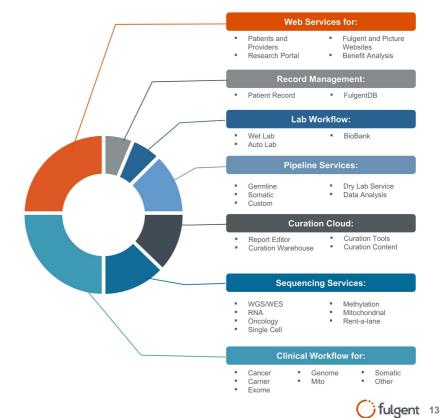
## **Proprietary Technology Platform**

#### **Differentiated Technology...**

- Engineered genetic biochemistry, including reagents and probes
- Data suppression and comparison algorithms
- Adaptive learning software
- Automated reporting

#### ...Provides a Multitude of **Advantages**

- Broad test menu
- Ability to rapidly develop and launch new
- Customizable test offerings
- Lower costs per billable test
- High efficiency



# **Broad Capabilities**



**Next Generation Sequencing** Opportunities

#### Recent Traction with:

- Hereditary Cancer
- Cardiovascular Genetics
- Reproductive Health
- Neurodegenerative Genetics

Newly launched pharmacogenetic

Aggressively expanding sales and commercial organization



#### Specialized **Oncology Testing**

Wide Array of Technologies

#### Services Include:

- Flow cytometry
- Cytogenetic analysis
- Fluorescence in-situ hybridization (FISH)
- Immunohistochemistry
- Molecular genetics
- Consultations in hematopathology and surgical pathology
- NGS



#### Comprehensive Anatomic Pathology Services

#### **Broad Capabilities**

- Breast pathology
  Gastrointestinal pathology
  Cormatonathology
  Gastrointestinal pathology
  Hematopathology
- Urologic pathology

Managed care contract network and physician relationships leveraged to provide diagnostic products and services complementary to Fulgent's portfolio

Expansive geographic presence with several CLIA-licensed laboratories across the United States



## **Technology/Platform Case Study: COVID-19**

Fulgent deployed its technology platform to rapidly respond to the COVID-19 Pandemic, scaling operations to provide tests with reliable results and rapid turnaround time



#### **Next Generation Sequencing** for COVID-19

- Research driven platform worked with local and federal government on genomic studies
- CDC contract awarded to Fulgent, worth up to \$47M to study SARS-CoV-2 using Fulgent's NGS platform
- Capacity of 10,000 NGS tests per day
- **Used** to identify new strains and mutations



#### Commercialized COVID-19 Testing Primarily RT-PCR Based Testing

#### Contracts with:

- School systems
- Nursing homes
- Athletic organizations
- Specialty health clinics
- Travel organizations
- Government agencies

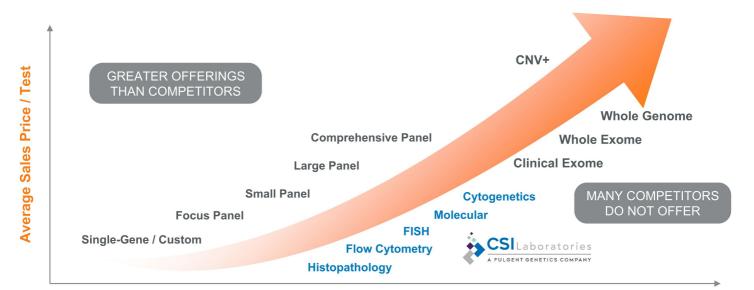
#### Offered through:

- Drive-through sites
- Picture at-home kits
- Managed on-site programs

Result: 19.3M COVID-19 tests delivered between 2020-2022, generating >\$1.7B in revenue for Fulgent



## Our Menu is Scalable and Affordable to Customers



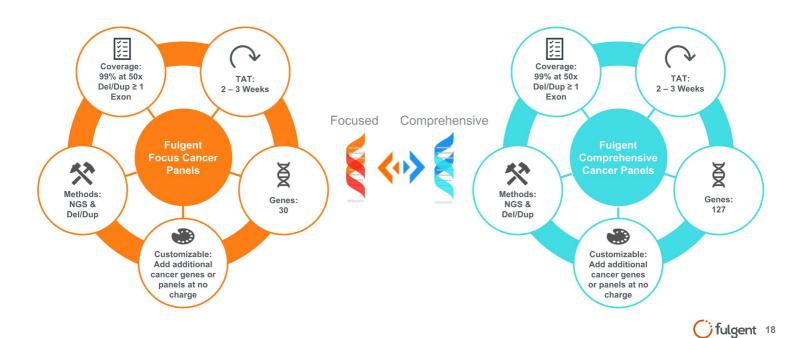


# **NGS Testing – Offerings**



C fulgent 17

# NGS Testing – Germline Oncology Test Menu



# **Oncology Testing Platforms**



- Expansive heme and solid tumor menu
- STAT testing available - PML/RARA <1 day
- CD138 cell enrichment for PCM
- 3-5 Day turnaround time



#### Histology

- 225+ stains
- Platform agnostic Roche, Agilent and Leica IHC
- Three levels of service -Tech Global Consultative
- PD-L1 Various IVD platforms and indications
- <1-2 Day turnaround



#### **Cytogenetics**

- Oncology and constitutional
- >20% abnormality detection rate
- Mitogen stimulation/dual culture
- DSP30 (detection of B-cell disorders)
- Interleukin 4 for plasma cell
- Phytohemagglutinin and Interleukin 2 (detection of Tcell disorders)
- Children's Oncology Group approved
- 5-7 Day turnaround time



## **Flow Cytometry**

- 10-color platform
- Comprehensive panel design
- High-sensitivity for paroxysmal nocturnal hemoglobinuria
- Expert analysis and interpretation
- 12-24 Hour turnaround



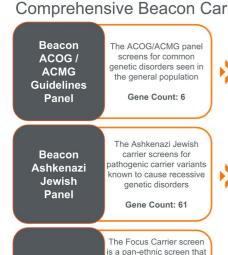
#### Molecular

- Hematology and solid tumor menu
- Extensive single gene menu
- NGS
- Solid tumor liquid biopsy NGS offering
- 5-7 Day turnaround time [NGS 10-14 Days]



# **NGS Testing – Panel Deep Dive**

## Comprehensive Beacon Carrier Screening Tests



Beacon

**Focus Panel** 

looks for pathogenic

mutations known to cause

autosomal recessive and X-linked disorders Gene Count: 30

The Expanded Panel screens for more than 400 recessive and X-linked Beacon conditions that covers people of all ethnic **Expanded** Panel backgrounds Gene Count: 427

> Beacon787 **Panel**

One of the largest panels available for those seeking the most comprehensive testing option

Gene Count: 787



#### **Beacon Carrier Screening**

- NGS of entire genes, not just hotspots
- Deletion and duplication analysis
- Proprietary algorithms for pseudogenes
- TAT: 2 Weeks



# NGS Testing – Reproductive Services: PGT-A

## PGT-A Can Expand a Patient's Prospects of a Successful Pregnancy



number of chromosomes have a better chance of resulting in successful

#### Reduced Risk of **Miscarriage**

Embryos with an abnormal number of chromosomes (aneuploid) typically do not result in successful pregnancy or may result in birth defects



## More Confidence in Transferring a Single **Embryo**

Avoid health risks associated with twin or triplet pregnancies that can occur from multiple embryo implantation

#### **Fewer Number of Embryo Transfer Cycles** Needed

Reduce the amount of time to pregnancy and the costs of additional IVF cycles



Preimplantation Genetic Testing for Aneuploidy (PGT-A) can identify potentially abnormal embryos for transfer in IVF, thereby expanding a patient's prospects of a successful pregnancy

Who is PGT-A testing for?

Women 35+

Those who have experienced miscarriages

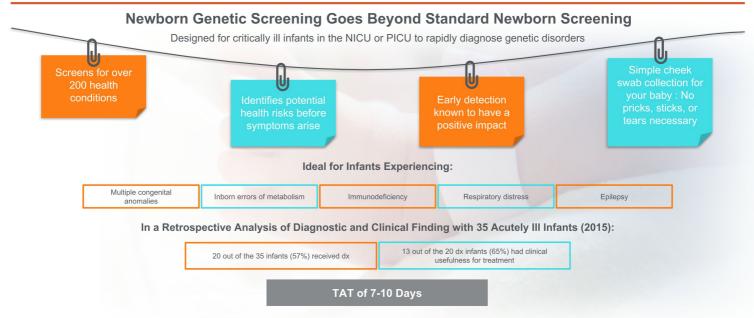
Those who want to reduce the likelihood of having multiples

Couples experiencing male factor infertility

Those who have experienced IVF failure



# NGS Testing - Rapid Whole Genome for Newborns



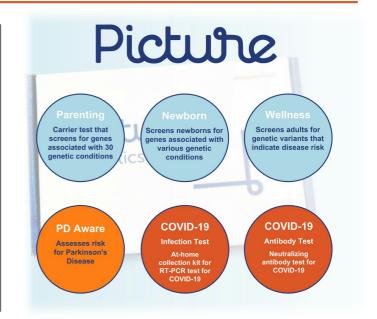
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## **Consumer Initiated Tests – Picture Genetics**

## Targeting the Large Consumer Market with Picture Genetics

Launched in 2019 with significant growth amid COVID-19

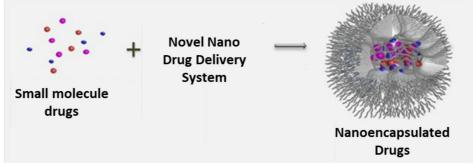
- A consumer-focused offering that merges clinical utility with accuracy of an accredited lab
- Extends Fulgent's NGS capabilities to a broader market
- Validated by successfully scaling to several million billable tests performed within months for COVID-19, after receiving an EUA
- Performs a complete sequencing (vs genotyping) analysis for better, more accurate results
- Patient-friendly with easy to use "order from home" model - no doctor visits or insurance necessary, though many tests are eligible for reimbursement
- Full service offering that includes analysis and genetic counseling support







## **Nano-Drug Delivery Platform Overview**



#### **Platform Advantage:**

Soluble in both water and various organic solvents and capable of hot melt mixing with APIs

- · Many drug candidates in the industry failed during preclinical and clinical development and testing due to poor water solubility
- Nanoencapsulation produces amorphous drug candidates with improved solubility and potentially enhanced absorption, drug PK profiles, safety and efficacy
- Broadly applicable to both IV and oral drug delivery formulations
- Potentially shortened development timeline
- · Plug and play drug delivery platform provides multiple shots on goal
- Simple and low-cost production process



## **FID-007 Program Overview**

#### FID-007 Phase I First in Human Clinical Trial -**Preliminary Findings**

- Dose levels up to 125 mg/m²/week with manageable safety profile, without yet reaching MTD
  - Dosing at 160 mg/m²/week is ongoing
- There is preliminary evidence of anti-tumor activity in heavily pre-treated patients across different tumor types
- Partial clinical data presented at ASCO 2021

A Phase 1 Trial of FID-007, a Novel Nanoparticle Paclitaxel Formulation, in Patients with Solid Tumors

Jacob Thomas<sup>1</sup>, Diane Habbi<sup>1</sup>, Dann Hamai<sup>2</sup>, Itene Kang<sup>1</sup>, Syma Içbal<sup>1</sup>, Jorge Nieva<sup>1</sup>, Derrice Tsao-Wei<sup>1</sup>, Francisco Acosta<sup>1</sup>,

Ming Hischi<sup>1</sup>, Yilong Zhang<sup>1</sup>, Anthony El-Khousin<sup>1</sup>.

<sup>1</sup>University of Southern California, Nortis Comprehensive Cancer Center <sup>2</sup>Houg Memorital Hospital; <sup>2</sup>Fulgent Pharma



#### FID-007 Phase I Preliminary Highlights (as of 6/10/22):

#### **H&N Cancer**

100% Disease Control Rate (DCR<sub>1</sub>) and 33% Overall Response Rate (ORR) were observed in 6 heavily treated **H&N** patients

#### Ampullary/Pancreatic

75% DCR and 50% ORR were seen in 4 heavily treated ampullary and pancreatic patients

#### Immune Checkpoint Inhibitors (ICIs) Resistant Patients

67% DCR and 33% ORR were seen in 6 heavily treated patients of different types of cancer with PD-1 or PD-L1 antibody treatment as the last line prior to enrollment in FID-007 trial

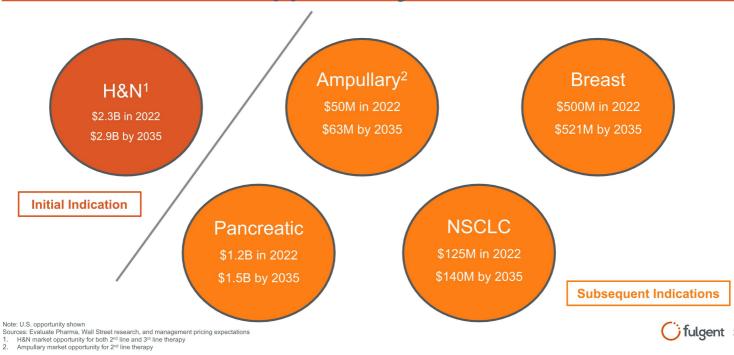
Anticipate more data to be published in 2023

Note: all findings are preliminary

1. DCR includes Stable Disease (SD), Partial Response (PR), Complete Response (CR)



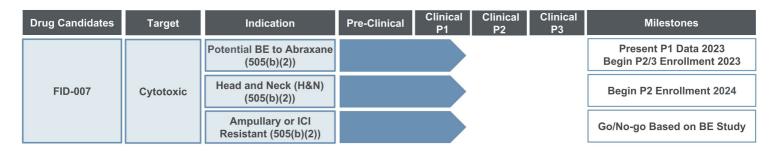
# **Potential Market Opportunity for FID-007**



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## FID-007 Clinical and Regulatory Plan

- Wholly-owned drug candidate initially focused on Head & Neck (H&N), Pancreatic/Ampullary cancers
  - Seeking initial therapeutic indication for 2<sup>nd</sup> or 3<sup>rd</sup> line treatment of H&N cancer
  - · Exploring potential ampullary or ICI resistant
- Potential FDA approval strategy uses 505(b)(2) studies, which may shorten clinical trial process and accelerate timeline to commercialization



Additional candidates in preclinical development focused on various cancers

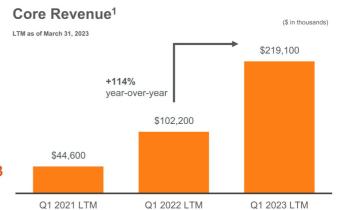


# FINANCIALS

# **Summary Financial Performance**

150% growth year-over-year

\$57M LTM Operating Cash Flow as of Q1'23



(1) Core Revenue excludes NGS COVID-19 test volume

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# Financial Performance: Revenue Profile



(1) Core Revenue excludes NGS COVID-19 test volume

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## 2023 Financial Guidance

	Q2 2023	Full Year 2023
		Raising FY 2023 Revenue
Core Revenue	\$62 M	\$250 M
Core Revenue	+ 37% y/y <sup>1</sup>	+ 38% y/y <sup>1</sup>
		FY 2023 EPS Reiterated
GAAP EPS	2	(\$2.50)
Non-GAAP EPS	2	(\$1.25)

Core growth reflects momentum across the business, including precision diagnostics, anatomic pathology, and pharma services

(1) Core Revenue excludes NGS COVID-19 test revenue for more accurate year over year comparison purposes (2) Refer to Full Year 2023 guidance.



# **Balance Sheet**

(in 000's)		Periods Ended					
		mber 31, 2022	March 31, 2023				
<u>Assets</u>							
Cash & cash equivalents	\$	79,506	\$	66,172			
Marketable securities		446,729		438,313			
Trade accounts receivable, net		52,749		43,549			
Other current assets		48,889		32,689			
Total current assets		627,873		580,723			
Marketable securities, long-term		326,648		366,833			
Redeemable preferred stock investment		12,385		12,982			
Fixed assets, net		81,353		79.083			
Intangible assets, net		150,643		148,699			
Goodwill		143,027		143,120			
Other long-term assets		44,124		45,327			
Total assets	\$	1,386,053	\$	1,376,767			
Liabilities and Stockholders' Equity							
Accounts payable	\$	23,093	\$	22,080			
Contract liabilities		3,199		2,733			
Customer deposit		10,895		11,621			
Investment margin loan		14,999		14,999			
Other liabilities		63,992		56,415			
Total liabilities		116,178		107,848			
Stockholders' equity		486,588		495,984			
Accumulated income		780,097		768,464			
Total Fulgent stockholders' equity		1,266,685		1,264,448			
Noncontrolling interest		3,190		4,471			
		1,269,875		1,268,919			
Total stockholders' equity		1,200,010		, ,			



# Non-GAAP Financial Adjustments

(in 000's)	2022			FY	2023	
	Q1	Q2	Q3	Q4	2022	Q1
Revenue	\$320,268	\$125,341	\$105,655	\$67,704	\$618,968	\$66,168
Cost of revenue	77,725	60,065	59,560	54,717	252,067	47,357
Gross profit	\$242,543	\$65,276	\$46,095	\$12,987	\$366,901	\$18,811
Gross margin	75.7%	52.1%	43.6%	19.2%	59.3%	28.4%
Equity-based compensation included in cost of revenue	1,465	2,243	2,475	2,521	8,704	2,394
Non-GAAP gross profit (excluding equity-based compensation)	\$244,008	\$67,519	\$48,570	\$15,508	\$375,605	\$21,205
Non-GAAP gross margin	76.2%	53.9%	46.0%	22.9%	60.7%	32.0%
Operating expenses						
Research and development	\$5,989	\$6,905	\$7,507	\$8,509	\$28,910	\$9,782
Selling and marketing	7,940	10,866	9,859	10,253	38,918	10,083
General and administrative	25,775	30,240	26,266	28,793	111,074	21,802
Amortization of intangible assets	906	1,575	2,006	2,010	6,497	1,968
Restructuring costs	_	2,896	105	(26)	2,975	_
Total operating expenses	40,610	52,482	45,743	49,539	188,374	43,635
Operating profit (loss)	\$201,933	\$12,794	\$352	(\$36,552)	\$178,527	(\$24,824)
Operating margin	63.1%	10.2%	0.3%	-54.0%	28.8%	-37.5%
Equity-based compensation included in operating expenses	4,151	5,787	6,497	7,501	23,936	7,871
Acquisition-related cost included in General and administrative	1,251	5,158	166	1,359	7,934	_
Non-GAAP operating profit (loss) (excluding equity-based compensation,						
amortization, restructuring costs & acquisition-related costs)	\$209,706	\$30,453	\$11,601	(\$23,187)	\$228,573	(\$12,591)
Non-GAAP operating margin	65.5%	24.3%	11.0%	-34.2%	36.9%	-19.0%

fulgent 34

