

**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): November 3, 2023

**FULGENT GENETICS, INC.**

(Exact Name of Registrant as Specified in Charter)

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

**001-37894**  
(Commission File Number)

**81-2621304**  
(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)

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 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(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
Common Stock, par value \$0.0001 per share	FLGT	The Nasdaq Stock Market (Nasdaq Global Market)

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

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 November 3, 2023, Fulgent Genetics, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended September 30, 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 November 3, 2023, the Company updated its investor presentation, which is available on the Investor Relations section of the Company’s website at <http://ir.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.

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release of Fulgent Genetics, Inc., dated November 3, 2023</a>
99.2	<a href="#">Corporate Presentation of Fulgent Genetics, Inc.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: November 3, 2023

FULGENT GENETICS, INC.

By: /s/ Paul Kim  
Name: Paul Kim  
Title: Chief Financial Officer

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## Fulgent Reports Third Quarter 2023 Financial Results

- Core Revenue of \$66 million represents Growth of 17% Year-over-Year
- Additional Reimbursement from COVID-19 Test Sales yields Revenue of \$19 million, for Total Revenue of \$85 million
- Reiterates Full Year 2023 Core Revenue Guidance of \$260 million

EL MONTE, CA, November 3, 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 third quarter ended September 30, 2023.

### Third Quarter 2023 Results:

- Total Revenue of \$85 million
- Core Revenue<sup>1</sup> grew 17% year-over-year to \$66 million
- GAAP loss of \$13.1 million, or \$0.44 per share
- Non-GAAP loss of \$11.7 million, or \$0.39 per share
- Adjusted EBITDA of \$18.1 million
- Generated cash flow from operations of \$10.2 million
- Cash, cash equivalents, and investments in marketable securities of \$851 million as of September 30, 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 continue to see good momentum in our core business, with particular strength in precision diagnostics. I am pleased with the trajectory of the business and our ability to use our resources efficiently as we continue to grow our core revenue. At the same time, we are advancing our therapeutics development business, Fulgent Pharma, with ongoing clinical data of our lead drug candidate, FID-007, being presented tomorrow at the Society for Immunotherapy of Cancer annual meeting in San Diego. We believe these data continue to support our program, and we are excited to initiate Phase 2 studies of FID-007 in head and neck cancer in the first quarter of 2024.”

Paul Kim, Chief Financial Officer, added, “We are pleased with our performance as we near the end of 2023, with momentum in the business and a strong financial profile. Even as we continue to invest in our business and repurchase shares, we are maintaining an enviable cash position with which to execute our strategy in 2024 and beyond.”

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**Outlook:**

For the full year 2023, Fulgent expects:

- Core Revenue of approximately \$260 million
- GAAP loss of approximately \$2.15 per share
- Non-GAAP loss of \$0.95 per share
- Cash, cash equivalents, and investments in marketable securities of approximately \$830 million as of December 31, 2023\*

\* Cash expenditures may be higher or lower than currently estimated due to a variety of facts and circumstances, including as a result of the Company's ongoing stock repurchase program or other expenditures outside of ordinary course.

**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 third quarter 2023 results. The call may be accessed through a live audio webcast on the Investor Relations section of the Company's website, <https://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 expenses, plus or minus the non-GAAP tax effect, and plus or minus other charges or gains, as identified, that management believes are not representative of the Company's operations. For the year 2022, 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 expenses. For the year 2023, the non-GAAP tax effect is calculated by excluding from the GAAP provision the impact of the amortization of intangible assets, restructuring costs, acquisition-related costs, and equity-based compensation expenses. 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 expenses, 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 income (loss) to calculate non-GAAP income (loss) and adjusted EBITDA income (loss); accordingly, the exclusion of these items in the presentation of these non-GAAP financial measures should not be construed as an implication that these

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items are unusual, infrequent or non-recurring. Management uses these non-GAAP financial measures along with the most directly comparable GAAP financial measure of net income (loss) in evaluating the Company's operating performance. 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 by Fulgent may not be comparable to similarly titled metrics reported by other companies.

## **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, the Company's cash position and sufficiency of its resources, momentum, trajectory, vision, future opportunities and future growth of the Company's testing services and technologies and expansion; the Company's research and development efforts, including any implications that the results of earlier clinical trials will be representative or consistent with later clinical trials and the expected timing of enrollment for these trials or the availability of data or results of these trials; 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

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base, which can fluctuate from period to 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 protect its proprietary technology and intellectual property. As a result of these risks and uncertainties, forward-looking statements should not be relied on or viewed as predictions of future events.

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 fiscal 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](mailto:melanie@blueshirtgroup.com)

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FULGENT GENETICS, INC.  
Condensed Consolidated Balance Sheet Data  
September 30, 2023 and December 31, 2022  
(in thousands)

	<u>September 30,</u>	<u>December 31,</u>
	<u>2023</u>	<u>2022</u>
<b>ASSETS:</b>		
Cash and cash equivalents	\$ 84,076	\$ 79,506
Investments in marketable securities	767,385	773,377
Accounts receivable, net	49,277	52,749
Property, plant, and equipment, net	85,265	81,353
Other assets	372,395	399,068
Total assets	<u>\$ 1,358,398</u>	<u>\$ 1,386,053</u>
<b>LIABILITIES &amp; EQUITY:</b>		
Accounts payable, accrued liabilities and other liabilities	\$ 96,564	\$ 116,178
Total stockholders' equity	1,261,834	1,269,875
Total liabilities & equity	<u>\$ 1,358,398</u>	<u>\$ 1,386,053</u>

FULGENT GENETICS, INC.  
**Condensed Consolidated Statement of Operations Data**  
**Three and Nine Months Ended September 30, 2023 and 2022**  
(in thousands, except per share data)  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue	\$ 84,687	\$ 105,655	\$ 218,708	\$ 551,264
Cost of revenue (1)	44,843	59,560	139,481	197,350
Gross profit	39,844	46,095	79,227	353,914
<b>Operating expenses:</b>				
Research and development (1)	10,014	7,507	29,488	20,401
Selling and marketing (1)	10,161	9,859	30,967	28,665
General and administrative (1)	17,498	26,266	57,293	82,281
Amortization of intangible assets	1,957	2,006	5,887	4,487
Restructuring costs	—	105	—	3,001
Total operating expenses	39,630	45,743	123,635	138,835
Operating income (loss)	214	352	(44,408)	215,079
Interest and other income, net	6,646	1,405	15,519	2,408
Income (loss) before income taxes	6,860	1,757	(28,889)	217,487
Provision for income taxes	20,326	414	12,016	51,488
Net (loss) income from consolidated operations	(13,466)	1,343	(40,905)	165,999
Net loss attributable to noncontrolling interests	359	376	1,229	1,236
Net (loss) income attributable to Fulgent	\$ (13,107)	\$ 1,719	\$ (39,676)	\$ 167,235
<b>Net (loss) income per common share attributable to Fulgent:</b>				
Basic	\$ (0.44)	\$ 0.06	\$ (1.33)	\$ 5.53
Diluted	\$ (0.44)	\$ 0.06	\$ (1.33)	\$ 5.38
<b>Weighted average common shares:</b>				
Basic	30,013	30,174	29,789	30,256
Diluted	30,013	30,867	29,789	31,107
<b>(1) Equity-based compensation expense was allocated as follows:</b>				
Cost of revenue	\$ 2,621	\$ 2,475	\$ 7,374	\$ 6,183
Research and development	3,782	2,687	10,900	7,110
Selling and marketing	1,189	1,243	3,644	3,148
General and administrative	3,310	2,567	9,572	6,177
Total equity-based compensation expense	\$ 10,902	\$ 8,972	\$ 31,490	\$ 22,618

FULGENT GENETICS, INC.

Non-GAAP Income (Loss) Reconciliation

Three and Nine Months Ended September 30, 2023 and 2022

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net (loss) income attributable to Fulgent	\$ (13,107)	\$ 1,719	\$ (39,676)	\$ 167,235
Amortization of intangible assets	1,957	2,006	5,887	4,487
Restructuring costs	—	105	—	3,001
Acquisition-related costs	—	166	—	6,575
Equity-based compensation expense	10,902	8,972	31,490	22,618
Non-GAAP tax effect (1)	(11,402)	(3,150)	(18,267)	(10,271)
Non-GAAP (loss) income attributable to Fulgent	<u>\$ (11,650)</u>	<u>\$ 9,818</u>	<u>\$ (20,566)</u>	<u>\$ 193,645</u>
Net (loss) income per common share attributable to Fulgent:				
Basic	\$ (0.44)	\$ 0.06	\$ (1.33)	\$ 5.53
Diluted	\$ (0.44)	\$ 0.06	\$ (1.33)	\$ 5.38
Non-GAAP (loss) income per common share attributable to Fulgent:				
Basic	\$ (0.39)	\$ 0.33	\$ (0.69)	\$ 6.40
Diluted	\$ (0.39)	\$ 0.32	\$ (0.69)	\$ 6.23
Weighted average common shares:				
Basic	30,013	30,174	29,789	30,256
Diluted	30,013	30,867	29,789	31,107

(1) Tax rates as follows:

Corporate tax rate of 28% for the three and nine months ended September 30, 2022. During the three months ended September 30, 2023, the Company established a valuation allowance for deferred tax assets.

**FULGENT GENETICS, INC.**  
**Non-GAAP Adjusted EBITDA Reconciliation**  
**Three and Nine Months Ended September 30, 2023 and 2022**  
**(in thousands)**

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Net (loss) income attributable to Fulgent	\$ (13,107)	\$ 1,719	\$ (39,676)	\$ 167,235
Interest income, net	(6,402)	(1,452)	(15,177)	(1,587)
Provision for income taxes	20,326	414	12,016	51,488
Restructuring costs	—	105	—	3,001
Acquisition-related costs	—	166	—	6,575
Equity-based compensation expense	10,902	8,972	31,490	22,618
Depreciation and amortization	6,419	9,820	19,610	22,860
Adjusted EBITDA	<u>\$ 18,138</u>	<u>\$ 19,744</u>	<u>\$ 8,263</u>	<u>\$ 272,190</u>

# Investor Presentation

November 3, 2023

Founded in 2011 | Located in Los Angeles, CA | NASDAQ:FLGT

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# Disclaimer

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## **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, 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 timelines, 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 forward-looking 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 forward-looking 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



**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



**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



**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 Clariant.

Chairman Emeritus of Pathology at City of Hope National Medical Center



**Dr. Ray Yin**  
President, Pharma

Founder & CEO, ANP Technologies, Inc.

Former Team Leader of Nanobiotechnology for Chem/Bio Defense, U.S. Army Research Laboratory

Holder of 46 drug delivery/detection patents



# 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

# 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



*Leading Genetic Testing Company Offering Tech-Enabled Diagnostic Solutions*



**Nano-Drug  
Delivery Platform**

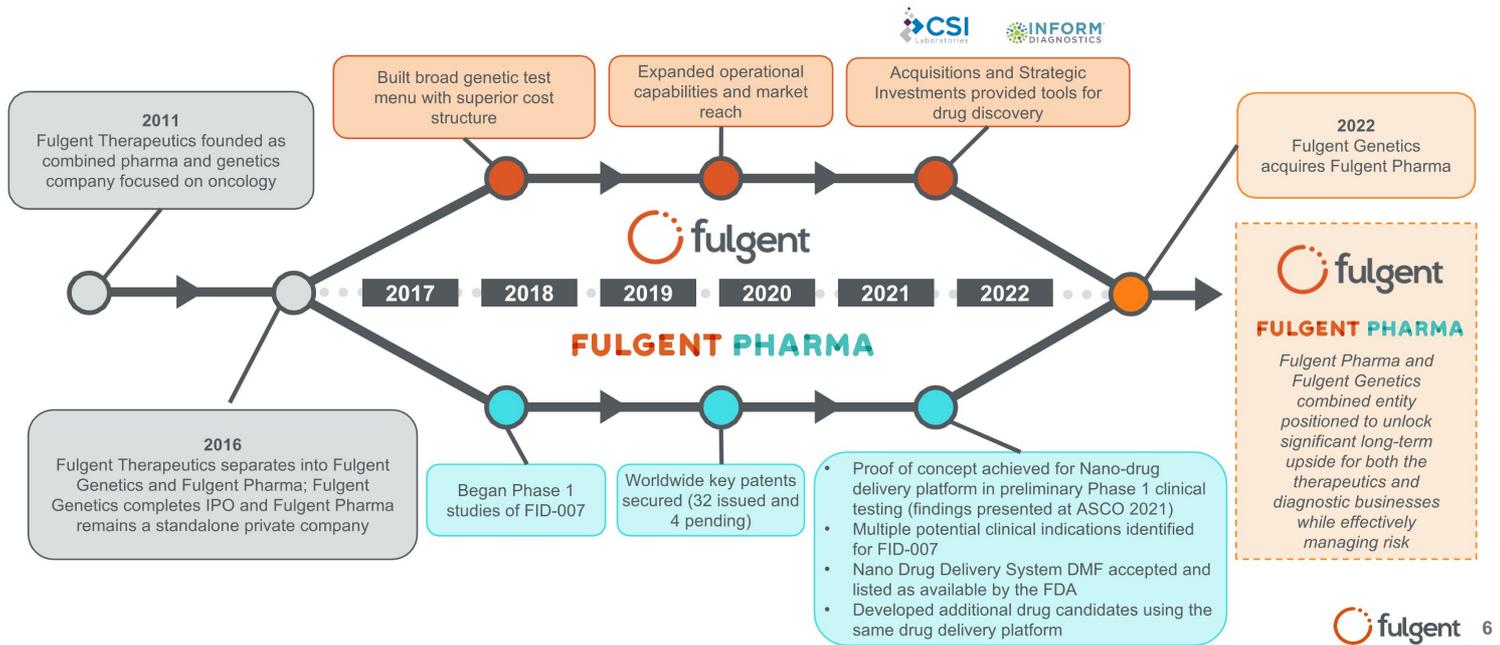
**FULGENT PHARMA**

*Exciting Cancer Therapeutic Opportunity  
Realizing Precision Medicine Potential*

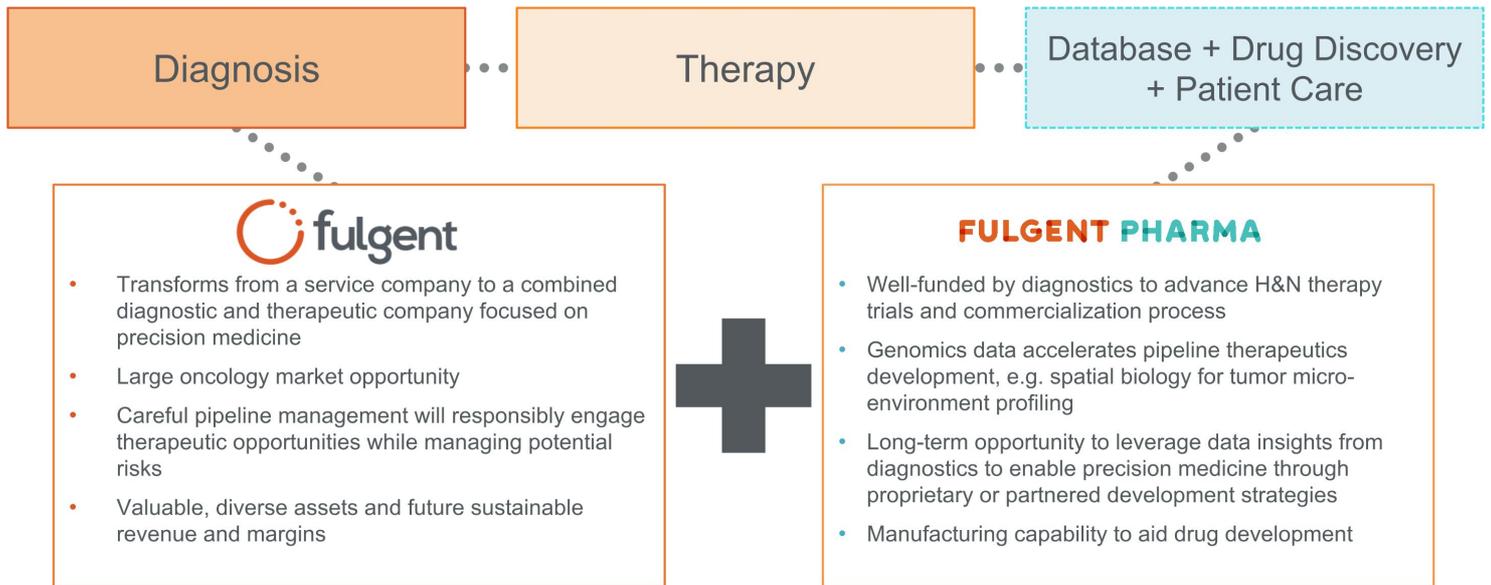
## **Therapeutic and Diagnostic Entity Providing Comprehensive Solutions Across the Cancer Care Continuum**

- 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 business
- 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

# History of Fulgent



# Long-Term Vision: Fulgent Continuum of Care



# DIAGNOSTICS



**\$85M**

Q3 Revenue

**+17%**

Q3 YoY Core Revenue Increase

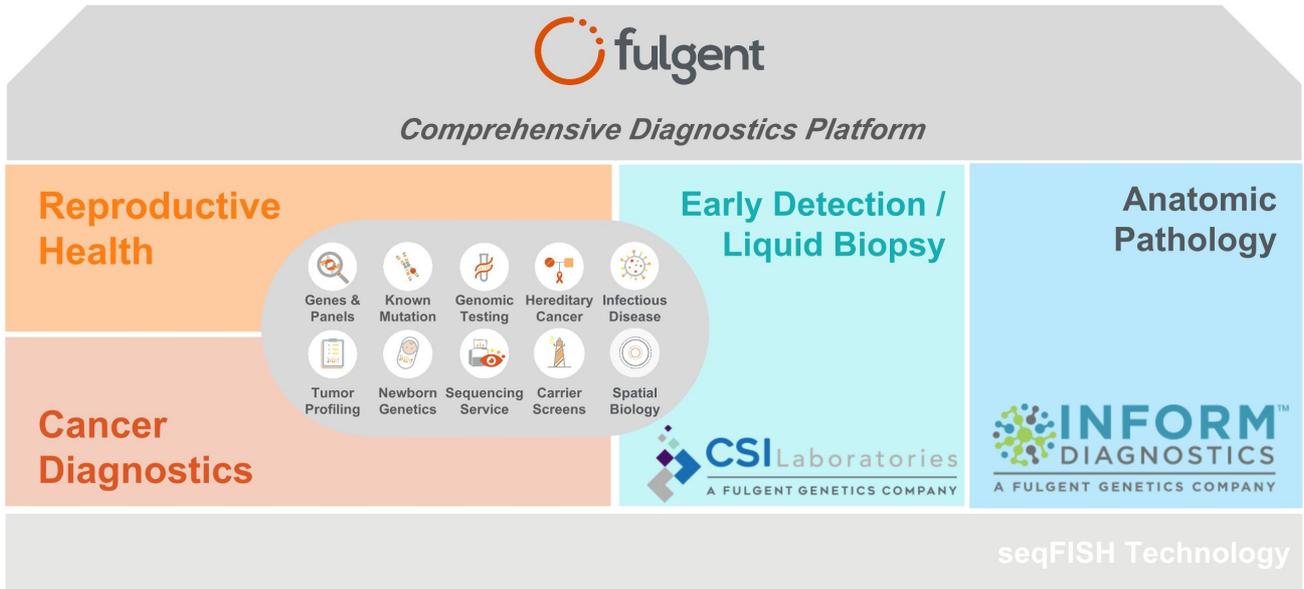
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18,400+ GENES | 900+ PANELS  
CUSTOMIZABLE OFFERINGS

## Positioned for Growth

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

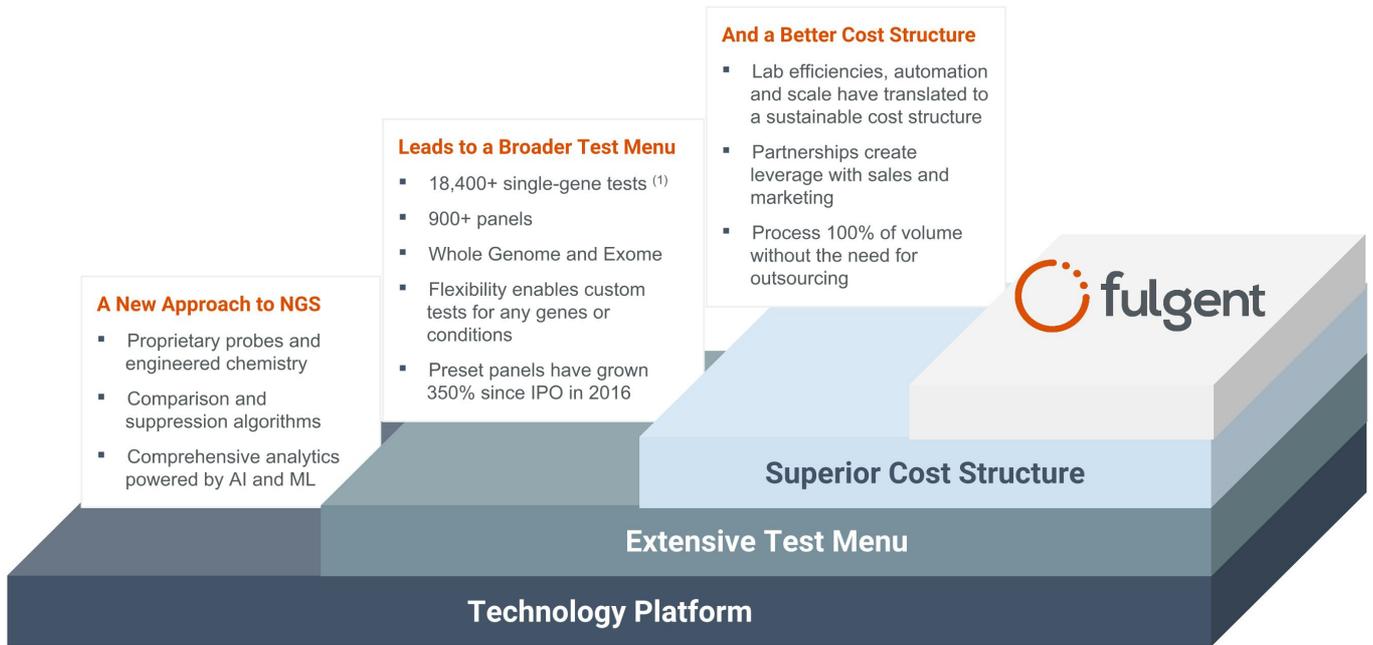
**\$8B market<sup>2</sup>**

## Pharma Services

**\$50B market<sup>3</sup>**

1) Market sizes sourced from Wall Street equity research  
2) Market size sourced from Frost & Sullivan, October 2022  
3) Market size sourced from Research and Markets, April 2022

# What Sets Fulgent Diagnostics Apart?



1) Represents genes covered by single-gene tests.

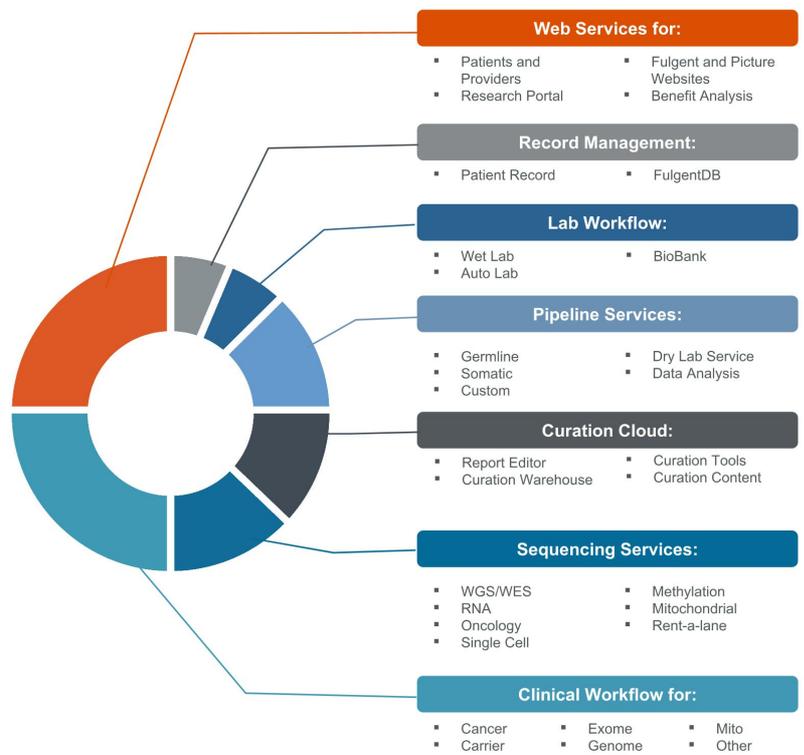
# Proprietary Technology Platform

## 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 tests
- Customizable test offerings
- Lower costs per billable test
- High efficiency



# Broad Capabilities

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## Next Generation Sequencing Opportunities

### Recent Traction with:

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

**Newly launched** pharmacogenetic test

**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
- Dermatopathology
- Urologic pathology
- Neuropathology
- Hematopathology

**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

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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:

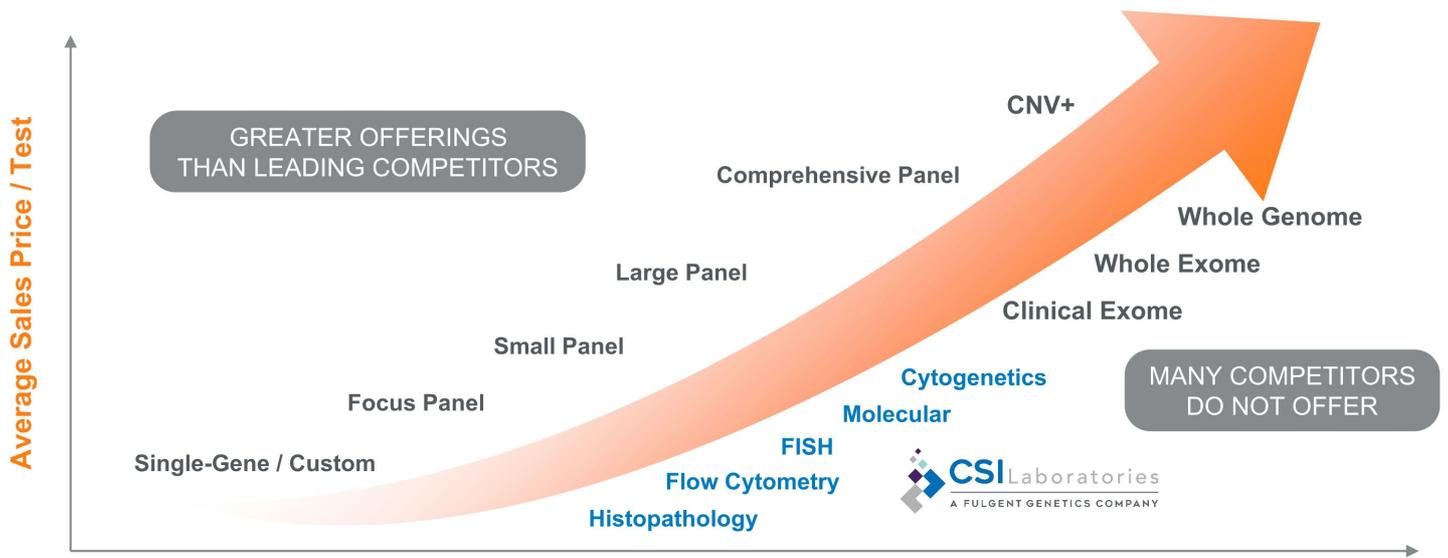
- School systems
- Nursing homes
- Athletic organizations
- Specialty health clinics
- Travel organizations
- Government agencies

### 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**

# Scalable and Affordable Menu for Customers



# NGS Testing – Offerings

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## Single Gene



18,400+ Genes

## Disease Panels



900+ Panels  
Customizable Panels

## Exome Tests



Clinical Exome (4,500+ Genes)  
Whole Exome

## Cancer Panels



Focus (30 Genes)  
Comprehensive (127 Genes)  
Somatic

## Known Mutation



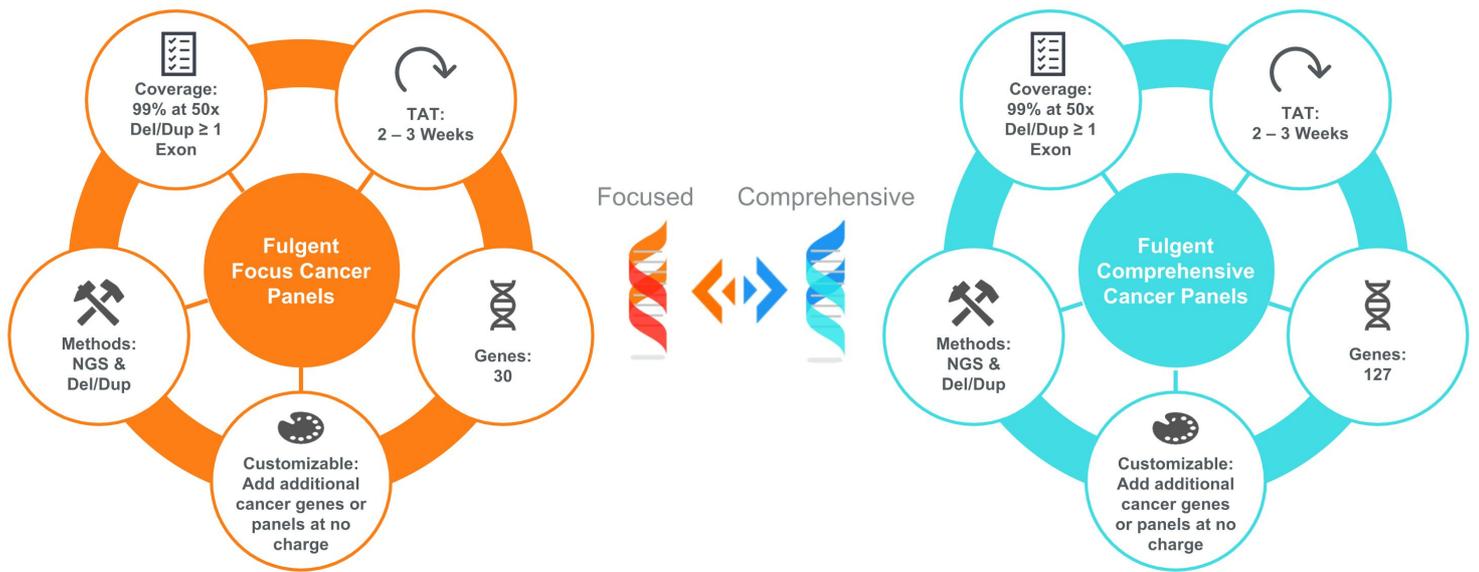
Site-Specific Testing

## Repeat Expansion



19 Panels

# NGS Testing – Germline Oncology Test Menu



# Oncology Testing Platforms

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## FISH

- Expansive heme and solid tumor menu
- STAT testing available - PML/RARA <1 day TAT
- 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 time



## Cytogenetics

- Oncology and constitutional
- >20% abnormality detection rate
- Mitogen stimulation/dual culture
- DSP30 (detection of B-cell disorders)
- Interleukin 4 for plasma cell myeloma
- Phytohemagglutinin and Interleukin 2 (detection of T-cell 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 time

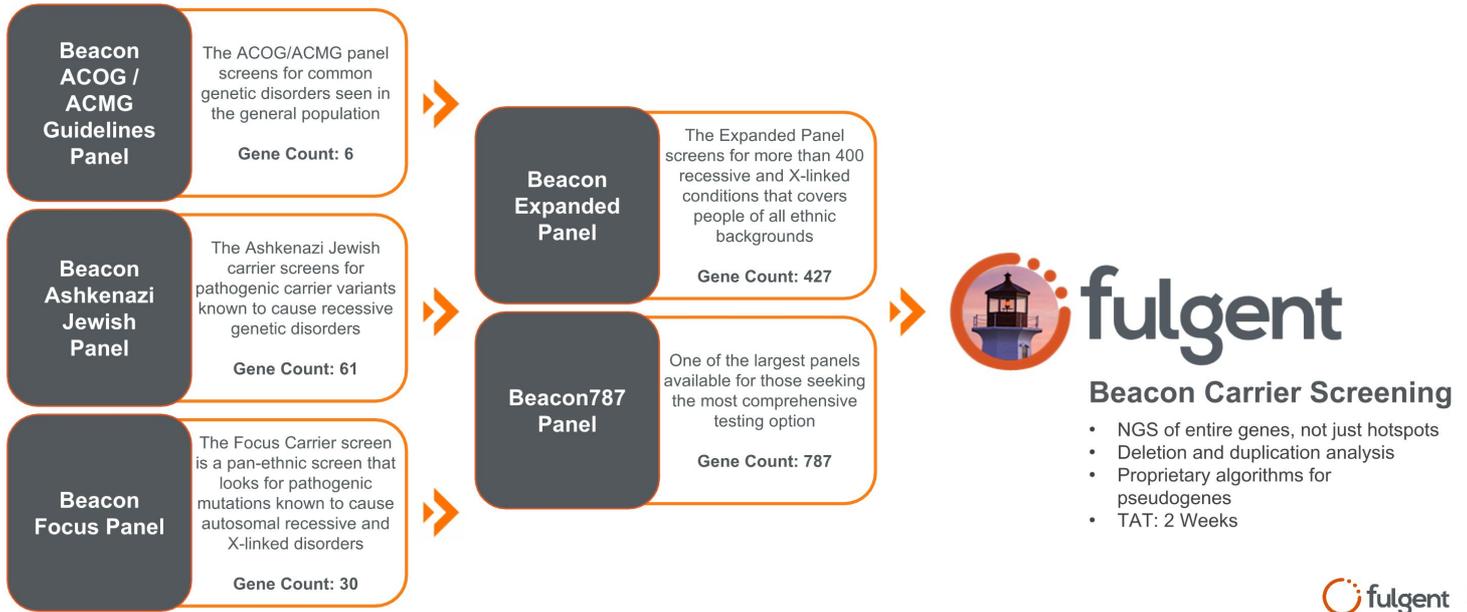


## Molecular

- Hematology and solid tumor menu
- Extensive single gene menu
- NGS
- Solid tumor liquid biopsy NGS offering
- 5-7 Day turnaround time [NGS 8-10 Days]

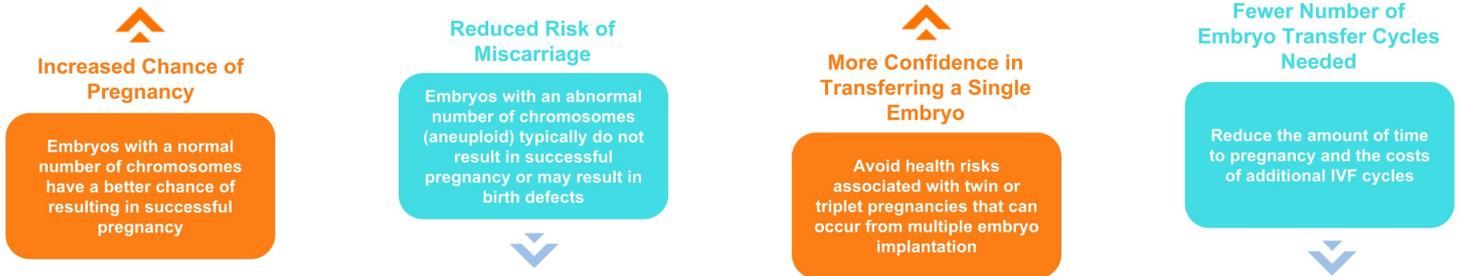
# NGS Testing – Panel Deep Dive

## Comprehensive Beacon Carrier Screening Tests



# NGS Testing – Reproductive Services: PGT-A

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



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
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# NGS Testing – Rapid Whole Genome for Newborns

## Newborn Genetic Screening Goes Beyond Standard Newborn Screening

Designed for critically ill infants in the NICU or PICU to rapidly diagnose genetic disorders

Screens for over 200 health conditions

Identifies potential health risks before symptoms arise

Early detection known to have a positive impact

Simple cheek swab collection for your baby : No pricks, sticks, or tears necessary

### Ideal for Infants Experiencing:

Multiple congenital anomalies

Inborn errors of metabolism

Immunodeficiency

Respiratory distress

Epilepsy

### In a Retrospective Analysis of Diagnostic and Clinical Finding with 35 Acutely Ill Infants (2015):

20 out of the 35 infants (57%) received dx

13 out of the 20 dx infants (65%) had clinical usefulness for treatment

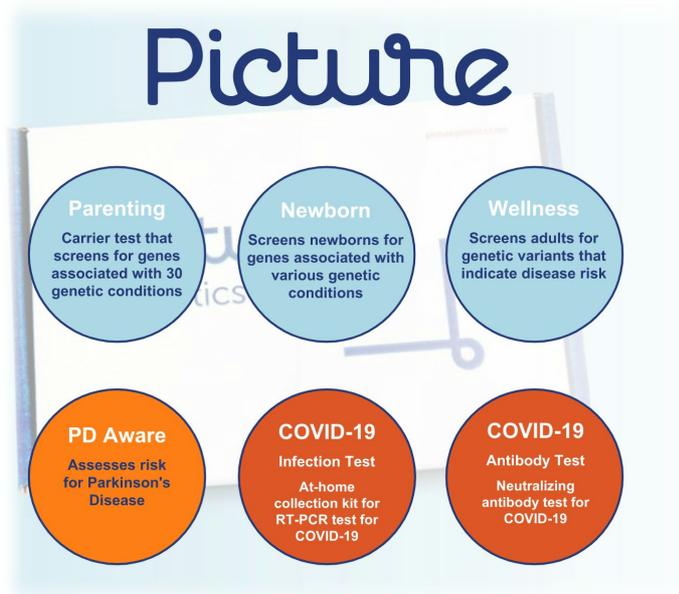
TAT of 7-10 Days

# Consumer Initiated Tests – Picture Genetics

## Targeting the Large Consumer Market with Picture Genetics

Launched in 2019 with significant growth amid COVID-19

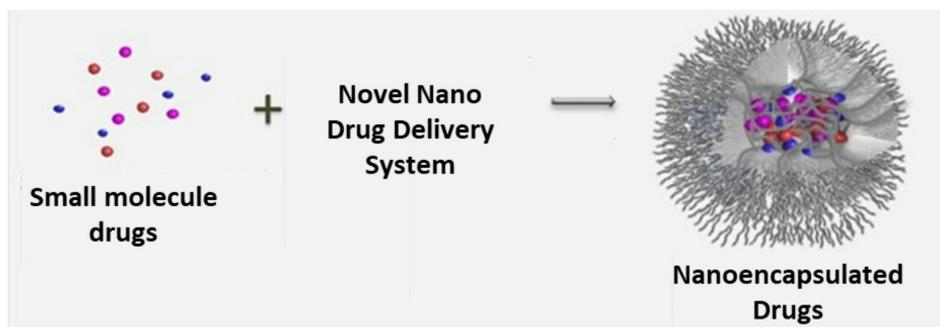
- A consumer-focused offering that merges clinical utility with accuracy of an accredited lab
- Extends Fulgent's NGS capabilities to a broader market
- Validated by **successfully scaling to several million billable tests** performed within months for COVID-19, after receiving an EUA
- Performs a complete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



# PHARMA



# 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 (n=40 patients)

- Dose levels up to 160 mg/m<sup>2</sup>/week with manageable safety profile
  - RP2D at 125 mg/m<sup>2</sup>/week
- There is preliminary evidence of anti-tumor activity in 40 heavily pre-treated patients across different tumor types (ORR = 18%)
- No high-grade neuropathy often seen in other taxanes
- Updated clinical data presented at ASCO 2023

## FID-007 Phase I Preliminary Highlights (as of 6/2/23):

### H&N Cancer

- 57% ORR and 71% DCR were observed in 7 heavily treated H&N patients. Among them, 6/7 had prior Taxane treatment.

### Ampullary/Pancreatic

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

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

Jacob Thomas<sup>1</sup>, Diane Habib<sup>1</sup>, Diana Hanna<sup>1,2</sup>, Irene Kang<sup>1</sup>, Syma Iqbal<sup>1</sup>, Jorge Nieva<sup>1</sup>, Denise Tsao-Wei<sup>1</sup>, Francisco Acosta<sup>1</sup>, Ming Hsieh<sup>3</sup>, Yikong Zhang<sup>3</sup>, Anthony El-Khoueiry<sup>1</sup>

<sup>1</sup>University of Southern California, Norris Comprehensive Cancer Center; <sup>2</sup>Hoag Memorial Hospital; <sup>3</sup>Fulgent Pharma



Note: all findings are preliminary

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

# FID-007 Clinical Data Presented at ASCO 2023

## Results

Table 1: Patient Baseline Characteristics		Table 2: Dose Levels Evaluated				
Characteristic	Overall, N = 40	Dose Level	FID-007 (mg/m <sup>2</sup> )	No. of Patients	No. of Evaluable Patients	DLT Type
Years of Age, Median (Range)	61 (52 - 75)	1	15	3	3	0
Gender		2	30	3	3	0
Female	23 (58%)	3	60	3	3	0
Male	17 (43%)	4	80	3	3	0
Race/Ethnicity		5	100	5	5	2*
White or Caucasian	11 (28%)	5b	100	4	3	0
Hispanic	19 (48%)	6	125	9	6	1
Black or African American	1 (3%)	7	160	3	3	1
Asian (including Indian)	9 (23%)	6a	125	7	6	1
ECOG PS						
0	11 (28%)					G3 febrile neutropenia
1	28 (70%)					Get neutropenia
2	1 (3%)					Get neutropenia
Number of Prior Regimens, Median (Range)	2 (1 - 5)					
Tumor Type						
Pancreatobiliary	11 (28%)					
Non-small cell lung	4 (10%)					
Head and neck SCC	11 (28%)					
Other	14 (35%)					

a. Two patients in dose level 5 had DLT of grade 3 maculopapular rash. Rash resolved with supportive care and/or dose delays in both patients and treatment was successfully continued safely without occurrence of grade 3 rash. DLT definition was modified for dose levels 5b and above to allow for grade 3 rash that resolves within 7 days. No further patients had DLT for rash in the subsequent dose levels.

b. Cohort 1b used modified pre-medication by removing sodium bicarbonate infusion and addition of corticosteroid pre-medication for C1 only. (See protocol for details)

Figure 1: Waterfall Plot for Best Response

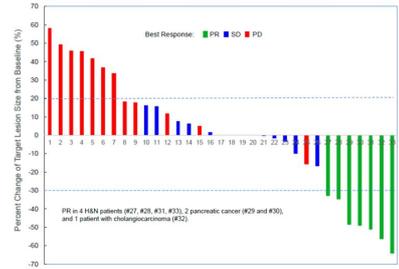


Table 4: Tumor Responses and Outcomes

Characteristic	Overall, N = 40
Total Courses Completed, Median (Range)	2 (1 - 30)
Best Response*	
PR	7 (18%)
SD	14 (35%)
PD <sup>a</sup>	18 (45%)
Duration of Follow-up (Months), Median (Range)	12.0 (0.4, 38.9)

a. PD includes 4 patients who had clinical deteriorations prior to RECIST evaluation.  
\* One patient response is pending

Table 3: Treatment-related select AE categories (≥= 10%)

Toxicity	Number of Patients With Maximum Grade Toxicity Experienced		
	Grade 1 or 2	Grade 3	Grade 4
Alopecia	21 (53%)	0	0
Rash maculo-papular	16 (40%)	11 (28%)	0
Pruritus	16 (40%)	0	0
Fatigue	15 (38%)	0	0
Anorexia	12 (30%)	1 (3%)	0
Nausea	12 (30%)	0	0
White blood cell decreased	11 (28%)	5 (13%)	3 (8%)
Anemia	10 (25%)	6 (15%)	0
Dyspeusia	10 (25%)	0	0
Neutrophil count decreased	9 (23%)	3 (8%)	5 (13%)
Peripheral sensory neuropathy	9 (23%)	0	0
Dry skin	8 (20%)	0	0
Palmar-plantar erythrodysesthesia syndrome	7 (18%)	0	0
Constipation	6 (15%)	0	0
Vomiting	6 (15%)	0	0
Diarrhea	5 (13%)	0	0
Arthralgia	4 (10%)	0	0
AST	4 (10%)	0	0

Figure 2: Swimmer Plot for Responses over Time

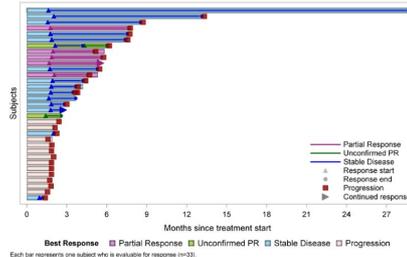
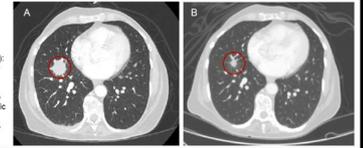


Figure 4: Partial Response in Patient with Head and Neck SCC

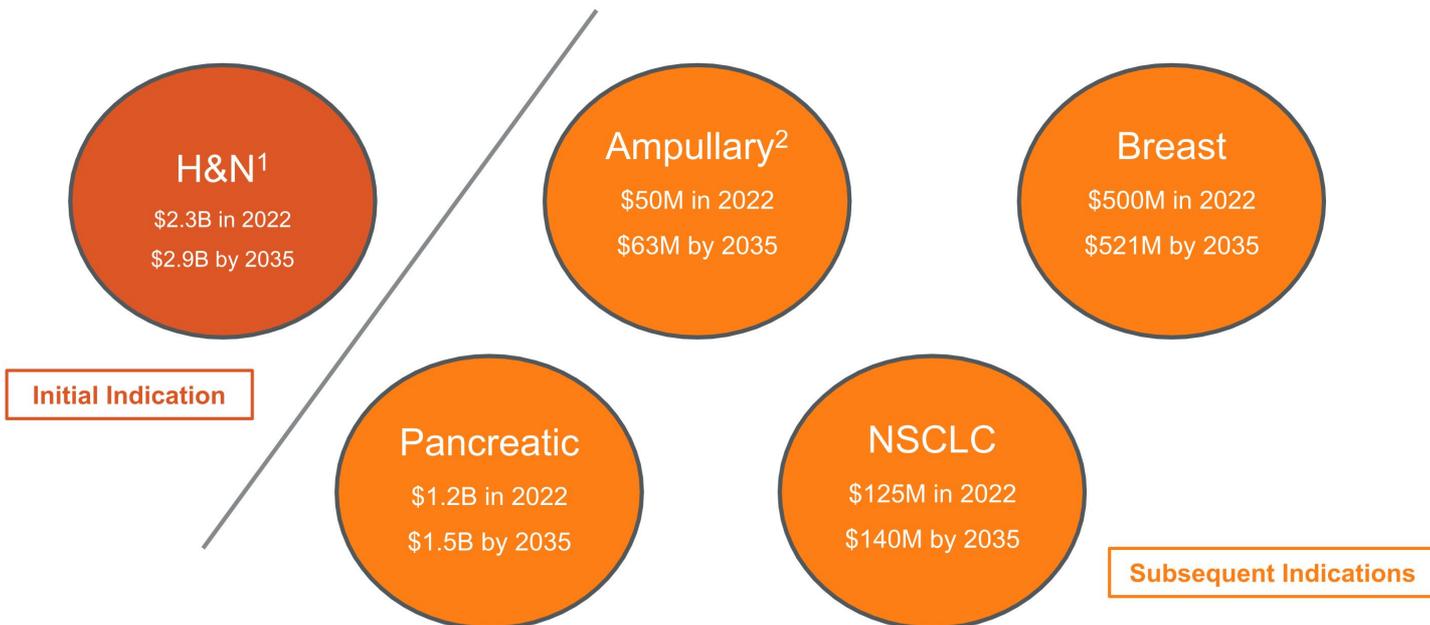
Panel A at baseline, panel B after 2 cycles of FID-007.  
Prior therapies (best response):  
- Pembrolizumab + 5-FU + capecitabine (SD)  
- Cetuximab (SD)  
- Docetaxel (PR 9 months)  
- NK cell + EGFR bi-specific Ab (PD)  
- Response ongoing > 6 months



## Conclusions

- Enrollment in a 10-patient expansion cohort at RP2D continues
- Based on overall tolerability, pharmacokinetics, and efficacy, the dose of 125mg/m<sup>2</sup> has been chosen as the RP2D.
- There has been no grade 3 or higher peripheral neuropathy
- Combination studies are planned, including a phase 2 study in head and neck SCC

# Potential Market Opportunity for FID-007



Note: U.S. opportunity shown  
Sources: Evaluate Pharma, Wall Street research, and management pricing expectations  
1. H&N market opportunity for both 2<sup>nd</sup> line and 3<sup>rd</sup> line therapy  
2. Ampullary market opportunity for 2<sup>nd</sup> line therapy

# Pipeline Progress

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

Drug Candidates	Target	Indication	Pre-Clinical	Clinical P1	Clinical P2	Clinical P3	Milestones
FID-007	Cytotoxic	Head and Neck (H&N) (505(b)(2))	▶				Begin P2 Enrollment in 1H24
		Ampullary or ICI Resistant (505(b)(2))	▶				Go/No-go Based on HN Study
FID-022	Cytotoxic	Colon (505(b)(2))	▶				IND Filing by YE24

*Additional new targeted therapies in preclinical development focused on various cancers*

# FINANCIALS



# Summary Financial Performance

**\$66M** Core Revenue<sup>1</sup> in Q3'23  
*17% growth year-over-year*

**\$45M** LTM Operating Cash Flow as of Q3'23

## Core Revenue<sup>1</sup>

LTM as of September 30, 2023

(\$ in thousands)

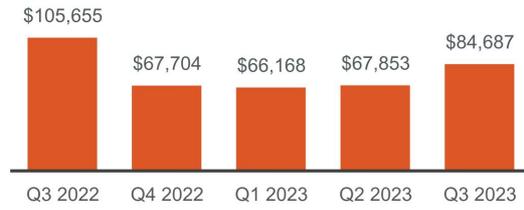


(1) Core Revenue excludes NGS COVID-19 test volume

# Financial Performance: Revenue Profile

## Total Revenue

(\$ in thousands)



## Core Revenue<sup>1</sup>

(\$ in thousands)



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

# 2023 Financial Guidance Reiterated

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

	Q4 2023	Full Year 2023
Core Revenue	\$64 M +16% y/y <sup>1</sup>	\$260 M +43% y/y <sup>1</sup>
GAAP EPS	-- <sup>2</sup>	(\$2.15)
Non-GAAP EPS	-- <sup>2</sup>	(\$0.95)

**Expected Cash, cash equivalents, and investments in marketable securities of approximately \$830 million as of December 31, 2023<sup>3</sup>**

(1) Core Revenue excludes NGS COVID-19 test revenue for more accurate year over year comparison purposes.

(2) Refer to Full Year 2023 guidance.

(3) Cash expenditures may be higher or lower than currently estimated due to a variety of facts and circumstances, including as a result of the Company's ongoing stock repurchase program or other expenditures outside of ordinary course.

# Balance Sheet

(in 000's)	Periods Ended	
	December 31, 2022	September 30, 2023
<b>Assets</b>		
Cash & cash equivalents	\$ 79,506	\$ 84,076 <sup>(1)</sup>
Marketable securities	446,729	383,726 <sup>(1)</sup>
Trade accounts receivable, net	52,749	49,277
Other current assets	48,889	32,776
<b>Total current assets</b>	<b>627,873</b>	<b>549,855</b>
Marketable securities, long-term	326,648	383,659 <sup>(1)</sup>
Redeemable preferred stock investment	12,385	15,158
Fixed assets, net	81,353	85,265
Intangible assets, net	150,643	144,489
Goodwill	143,027	141,844
Other long-term assets	44,124	38,128
<b>Total assets</b>	<b>\$ 1,386,053</b>	<b>\$ 1,358,398</b>
<b>Liabilities and Stockholders' Equity</b>		
Accounts payable	\$ 23,093	\$ 15,772
Contract liabilities	3,199	2,586
Customer deposit	10,895	18,861
Investment margin loan	14,999	-
Other liabilities	63,992	59,345
<b>Total liabilities</b>	<b>116,178</b>	<b>96,564</b>
Stockholders' equity	486,588	514,265
Accumulated income	780,097	744,433
<b>Total Fulgent stockholders' equity</b>	<b>1,266,685</b>	<b>1,258,698</b>
<b>Noncontrolling interest</b>	<b>3,190</b>	<b>3,136</b>
<b>Total stockholders' equity</b>	<b>1,269,875</b>	<b>1,261,834</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 1,386,053</b>	<b>\$ 1,358,398</b>

(1) \$851M in cash and investments.

# Non-GAAP Financial Adjustments

(in 000's)	2022				FY 2022	2023		
	Q1	Q2	Q3	Q4		Q1	Q2	Q3
<b>Revenue</b>	\$320,268	\$125,341	\$105,655	\$67,704	\$618,968	\$66,168	\$67,853	\$84,687
Cost of revenue	77,725	60,065	59,560	54,717	252,067	47,357	47,281	44,843
Gross profit	\$242,543	\$65,276	\$46,095	\$12,987	\$366,901	\$18,811	\$20,572	\$39,844
Gross margin	75.7%	52.1%	43.6%	19.2%	59.3%	28.4%	30.3%	47.0%
Equity-based compensation included in cost of revenue	1,465	2,243	2,475	2,521	8,704	2,394	2,359	2,621
<b>Non-GAAP gross profit (excluding equity-based compensation)</b>	\$244,008	\$67,519	\$48,570	\$15,508	\$375,605	\$21,205	\$22,931	\$42,465
<b>Non-GAAP gross margin</b>	76.2%	53.9%	46.0%	22.9%	60.7%	32.0%	33.8%	50.1%
<b>Operating expenses</b>								
Research and development	\$5,989	\$6,905	\$7,507	\$8,509	\$28,910	\$9,782	\$9,692	\$10,014
Selling and marketing	7,940	10,866	9,859	10,253	38,918	10,083	10,723	10,161
General and administrative	25,775	30,240	26,266	28,793	111,074	21,802	17,993	17,498
Amortization of intangible assets	906	1,575	2,006	2,010	6,497	1,968	1,962	1,957
Restructuring costs	—	2,896	105	(26)	2,975	—	—	—
Total operating expenses	40,610	52,482	45,743	49,539	188,374	43,635	40,370	39,630
Operating profit (loss)	\$201,933	\$12,794	\$352	(\$36,552)	\$178,527	(\$24,824)	(\$19,798)	\$214
Operating margin	63.1%	10.2%	0.3%	-54.0%	28.8%	-37.5%	-29.2%	0.3%
Equity-based compensation included in operating expenses	4,151	5,787	6,497	7,501	23,936	7,871	7,964	8,281
Acquisition-related cost included in General and administrative	1,251	5,158	166	1,359	7,934	—	—	—
<b>Non-GAAP operating profit (loss) (excluding equity-based compensation, amortization, restructuring costs &amp; acquisition-related costs)</b>	\$209,706	\$30,453	\$11,601	(\$23,187)	\$228,573	(\$12,591)	(\$7,513)	\$13,073
<b>Non-GAAP operating margin</b>	65.5%	24.3%	11.0%	-34.2%	36.9%	-19.0%	-11.1%	15.4%

**THANK YOU**





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