Illumina, Inc.

(Exact name of registrant as specified in its charter)

001-35406
(Commission File Number)

Delaware
(State or other jurisdiction of incorporation)

33-0804655
(I.R.S. Employer Identification No.)

5200 Illumina Way, San Diego, CA 92122
(Address of principal executive offices) (Zip code)

(858) 202-4500
(Registrant’s telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

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

☐ Written 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:

<table>
<thead>
<tr>
<th>Title of each class</th>
<th>Trading Symbol(s)</th>
<th>Name of each exchange on which registered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Stock, $0.01 par value</td>
<td>ILMN</td>
<td>The NASDAQ Stock Market LLC</td>
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</tbody>
</table>

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 13a of the Exchange Act. ☐
As previously disclosed, on August 18, 2021, pursuant to the Agreement and Plan of Merger, dated as of September 20, 2020, as amended, by and among Illumina, Inc., a Delaware corporation (“Illumina”), GRAIL, Inc., a Delaware corporation (together with any successor entity, “GRAIL”), and the other parties thereto, Illumina completed its acquisition of GRAIL, Inc. (the “Acquisition”).

Also as previously disclosed, on April 19, 2021, the European Commission accepted a request for referral of the Acquisition (the “Referral”) for European Union merger review under Article 22(1) of Council Regulation (EC) No 139/2004 (the “EU Merger Regulation”), which had been submitted by a Member State of the European Union.

Also as previously disclosed, on April 29, 2021, Illumina filed an action in the General Court of the European Union (the “EU General Court”) asking for annulment of the European Commission’s decision asserting jurisdiction to review the Acquisition under Article 22 of the EU Merger Regulation. On July 13, 2022, the EU General Court ruled that the European Commission has jurisdiction to review the Acquisition under Article 22(1) of the EU Merger Regulation. Illumina disagrees with the EU General Court’s decision and intends to file its appeal to the Court of Justice of the European Union.

On September 6, 2022, the European Commission announced that it had completed its Phase II review of the Acquisition and adopted a final decision (the “Prohibition Decision”), which found that, in its view, Illumina’s acquisition of GRAIL was incompatible with the internal market in Europe because it results in a significant impediment to effective competition. Public statements made by the European Commission in connection with the Prohibition Decision indicate that a subsequent decision is likely to be adopted by the European Commission that will order Illumina to divest GRAIL (an “EC Divestment Decision”). Neither the Prohibition Decision nor such public statements indicate when any such EC Divestment Decision may be adopted.

Illumina intends to appeal the Prohibition Decision to the EU General Court. Illumina also intends to appeal any EC Divestment Decision (if and when adopted by the European Commission) and, if necessary, to seek interim relief suspending the divestment of GRAIL until the final determination of these appeals.

The Prohibition Decision and an EC Divestment Decision, and any order or decision by the U.S. Federal Trade Commission pursuant to which Illumina is required to divest GRAIL (together with an EC Divestment Decision, a “Divestment Decision”), if implemented once final and non-appealable or during the pendency of the applicable appeals proceedings, and Illumina’s obligations pursuant thereto, will impose significant costs and additional liabilities on Illumina, including significant advisory fees and additional expenses, and may result in loss of revenue and other adverse effects on Illumina’s business, financial condition and results of operations. Such adverse effects could include Illumina being required to divest GRAIL on terms that are materially worse than the terms on which Illumina acquired GRAIL. For example, Illumina will not be able to, in a sale of GRAIL, effect such sale in a non-taxable transaction and so will incur significant tax liabilities attributable to the recognition of taxable gain equal to the difference between (i) the fair market value of any consideration received and (ii) Illumina’s tax basis in GRAIL (which tax basis is currently estimated to be approximately $700 million). Furthermore, the Prohibition Decision and the implementation of a Divestment Decision could divert management’s attention and company resources away from existing operations and other opportunities that may have been beneficial to Illumina, any or all of which, individually or in the aggregate, could have a material adverse effect on Illumina’s business, financial condition and results of operation. Illumina cannot predict what other adverse consequences to, among other things, its reputation, its relationships with governmental or regulatory authorities or its ability to successfully complete future transactions may result.

On September 6, 2022, Illumina issued a press release addressing the Prohibition Decision. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.
Cautionary Notes on Forward-Looking Statements

This communication contains “forward-looking statements” within the meaning of the federal securities laws, including Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In this context, forward-looking statements often address expected future business and financial performance and financial condition, and often contain words such as “expect,” “anticipate,” “intend,” “plan,” “believe,” “seek,” “see,” “will,” “would,” “may,” “target,” similar expressions and variations or negatives of these words. Forward-looking statements by their nature address matters that are, to different degrees, uncertain, such as statements about the effects of the consummation of the transaction and the anticipated benefits thereof. These and other forward-looking statements are not guarantees of future results and are subject to risks, uncertainties and assumptions that could cause actual results to differ materially from those expressed in any forward-looking statements. Important risk factors that may cause such a difference include, but are not limited to: (i) the terms and conditions of any required divestiture of GRAIL, and the timing of and the risks, costs and business disruptions (including the diversion of management’s attention) associated with any such divestiture, the announcement, pendency or implementation thereof or any associated legal or regulatory proceedings or obligations, and other uncertainties related to Illumina’s compliance (or ability to comply) with a Divestment Decision, which may adversely affect Illumina and its business, including current plans and operations; (ii) the possibility of other adverse consequences to, among other things, Illumina’s reputation, its relationships with governmental or regulatory authorities or its ability to successfully complete future acquisitions and/or divestitures as a result of the Acquisition, the Prohibition Decision or a Divestment Decision; (iii) the potential impact of unforeseen liabilities, future capital expenditures, revenues, costs, expenses, earnings, dis-synergies, economic performance, indebtedness, financial condition and losses on the future prospects, business and management strategies for the management, expansion and growth of Illumina’s business following or in connection with any divestiture of GRAIL; (iv) potential adverse reactions or changes to business relationships or our ability to attract and retain employees resulting from the announcement, pendency or implementation of the Decisions and/or legal, regulatory and other proceedings related thereto; (v) any negative effects of the announcement, pendency or implementation of the Prohibition Decision or a Divestment Decision and/or of any divestiture of GRAIL on the market price of Illumina’s common stock and on Illumina’s operating results; (vi) risks associated with third-party contracts or other agreements containing provisions that might be implicated by any divestiture of GRAIL, including Illumina’s obligations with respect to certain GRAIL contingent value rights and the risk that Illumina will be unable to fully discharge such obligations in connection with a divestiture of GRAIL; (vii) the risk that Illumina will be unable to recover the costs and/or realize the economic benefits associated with its efforts to develop and commercialize GRAIL’s products, including Galleri, the cancer screening test developed by GRAIL; (viii) the risk that Illumina’s appeals of the Prohibition Decision or a Divestment Decision and the EU General Court’s ruling on the European Commission’s jurisdiction to review the Acquisition and impose any decisions with respect thereto or the Decisions and any of other negative outcomes of legal, regulatory and other proceedings related thereto; (ix) the risk of adverse effects resulting from additional potential litigation associated with the Acquisition; (x) the other risks described in Illumina’s most recent annual reports on Form 10-K and quarterly reports on Form 10-Q and (xi) management’s response to any of the aforementioned factors.

While the list of factors presented here is, and the list of factors presented in Illumina’s public filings are, considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Consequences of material differences in results as compared with those anticipated in the forward-looking statements could include, among other things, business disruption, operational problems, financial loss, legal liability to third parties and similar risks, any of which could have a material adverse effect on Illumina’s financial condition, results of operations, credit rating or liquidity. Illumina does not assume any obligation to publicly provide revisions or updates to any forward-looking statements, whether as a result of new information, future developments or otherwise, should circumstances change, except as otherwise required by securities and other applicable laws.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release dated September 6, 2022 issued by Illumina, Inc.
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: September 6, 2022

By: /s/ CHARLES E. DADSWELL
Name:Charles E. Dadswell
Title: Senior Vice President, General Counsel and Secretary
Illumina Intends to Appeal European Commission’s Decision in GRAIL Deal

SAN DIEGO, September 6, 2022 /PRNewswire/ -- Illumina, Inc. (NASDAQ:ILMN), today received a decision from the European Commission prohibiting the company’s acquisition of GRAIL. The company is reviewing the Commission’s order and intends to appeal the decision. The EC decision follows last week’s ruling by US Federal Trade Commission judge in favor of Illumina’s acquisition of GRAIL.

“We are disappointed with the European Commission’s decision prohibiting us from acquiring GRAIL back to Illumina,” said Charles Dadswell, General Counsel of Illumina. “Illumina can make GRAIL’s life-saving multi-cancer early detection test more available, more affordable, and more accessible – saving lives and lowering healthcare costs. As we continue to believe, this merger is pro-competitive and will accelerate innovation. Last week the Chief Judge of the US Federal Trade Commission issued a decision supporting Illumina acquiring GRAIL.”

In addition, to prepare for the anticipated divestment order from the European Commission in the coming months, the company will begin reviewing strategic alternatives for GRAIL in the event the divestiture is not stayed pending Illumina’s appeal.

The merger of Illumina and GRAIL would usher in a transformational phase in the detection and treatment of cancer by facilitating equal and affordable access to the life-saving early cancer detection Galleri test.

With a single blood test, Galleri can screen asymptomatic patients for more than 50 types of cancer, many of which have no other form of screening and are often caught too late to treat effectively. In addition, Galleri can identify the tissue in which a cancer has developed. Galleri is unique as a multicancer early detection test suitable for general population screening. There is no other test available for this purpose. Galleri is available today in the US and the UK, but not in the European Union.

Illumina would accelerate GRAIL’s commercial entry into the EU at scale by at least five years, saving tens of thousands of lives in the EU and billions of euros in healthcare costs.

A combined Illumina and GRAIL is key to helping the European Union achieve the goals outlined in Europe’s Beating Cancer Plan, which states: “Early detection through screening offers the best chance of beating cancer and saving lives.” Today, 71% of cancer-related deaths are in cancers with no recommended screening. With limited screening, cancer is more likely to be detected in late stages but when we diagnose cancer too late, less than 20% of patients will survive more than 5 years. In contrast, if we diagnose cancer early, approximately 90% of patients are expected to survive beyond five years. The GRAIL merger would not only accelerate multicancer early detection in the EU but would also reduce inequity in cancer care by making early diagnosis affordable and widespread, another key priority of Europe’s Beating Cancer Plan.

1 Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov)
Illumina is separately appealing a July 2022 decision by the General Court of the European Union regarding the European Commission’s jurisdiction to challenge the GRAIL deal.

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About Illumina
Illumina is improving human health by unlocking the power of the genome. Our focus on innovation has established us as a global leader in DNA sequencing and array-based technologies, serving customers in the research, clinical, and applied markets. Our products are used for applications in the life sciences, oncology, reproductive health, agriculture, and other emerging segments. To learn more, visit illumina.com and connect with us on Twitter, Facebook, LinkedIn, Instagram, and YouTube.

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