# 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): September 24, 2019

# ADAPTIVE BIOTECHNOLOGIES CORPORATION

(Exact name of Registrant as Specified in Its Charter)

Washington (State or Other Jurisdiction of Incorporation) 001-38957

(Commission File Number)

27-0907024 (IRS Employer Identification No.)

1551 Eastlake Avenue East, Suite 200, Seattle, Washington (Address of Principal Executive Offices)

98102 (Zip Code)

Registrant's Telephone Number, Including Area Code: (206) 659-0067

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

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

□ Written 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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-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:

	Trading	
Title of each class	Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	ADPT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 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  $\boxtimes$ 

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 1.01 Entry into a Material Definitive Agreement.

On September 24, 2019, Adaptive Biotechnologies Corporation (the "*Company*") entered into a non-exclusive development and supply agreement (the "*Agreement*") with Illumina, Inc., a supplier of sequencing products and equipment to the Company ("*Illumina*"), with respect to the Company's development and commercialization of in-vitro diagnostic test kits for clonoSEQ<sup>®</sup> and immunoSEQ  $Dx^{TM}$  ("*IVD Kits*"). The clonoSEQ IVD Kits will utilize the Company's current assays for the assessment and monitoring of minimal residual disease in connection with treatment or management of patients with lymphoid malignancies while the immunoSEQ Dx IVD kits will provide access to the Company's pipeline immunodiagnostics applications as they are developed.

The Agreement provides that Illumina will develop custom software ("*Custom Software*") for the Company to support use of the IVD Kits by customers on Illumina's clinical diagnostic sequencing instrument, NextSeqDx<sup>®</sup>. In addition, Illumina will provide regulatory and related support for the components of the IVD Kits related to Illumina components or Custom Software. Illumina will retain ownership of the Custom Software to be developed, subject to an exclusive license to the Company. Company will retain ownership of the IVD Kits. Each party will be responsible for distributing and otherwise commercializing its respective products to end users.

The Company agrees to pay Illumina: (i) two technology access milestone payments related to development of the Custom Software modules payable upon: (a) Company acceptance of a verified Custom Software module that meets the specification requirements set forth in the development plan for the first IVD Kit; and (b) installation of the Custom Software module at a clinical trial site; and (ii) tiered revenue share payments on net sales (subject to certain customary reductions) of the IVD Kits ranging from a low to mid-single digit percentage of future net sales. For use during the development phase of the Agreement, the Company will purchase instruments and consumables from Illumina as needed to support the pre-commercial development of the IVD Kits.

The term of the Agreement expires on September 24, 2025. Either the Company or Illumina may terminate the Agreement in the case of (i) a material breach by the other party after providing notice and an opportunity to cure; (ii) in the case of bankruptcy or insolvency of the other party; or (iii) if at any time after September 24, 2021 there are no active development plans in place. The Agreement contains customary representations, warranties, covenants, indemnities and other obligations of the parties as well as Company reporting and forecasting requirements with respect to the IVD Kits and their components.

The foregoing descriptions of the Agreement are not complete and are qualified in their entirety by reference to the full text of the Agreement. A copy of the Agreement will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 (with certain portions subject to confidential treatment). On September 24, 2019, the Company and Illumina issued a joint press release announcing the entry into the Agreement. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

#### Item 7.01 Regulation FD Disclosure.

On September 24, 2019, the Company issued a press release relating to the Agreement, a copy of which is attached as Exhibit 99.1 and incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in the press release attached as Exhibit 99.1 hereto shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*"), nor shall such information be deemed incorporated by reference in any 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 Number	Description				
99.1	Press Release dated September 24, 2019				
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# SIGNATURES

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 thereunto duly authorized.

Date: September 24, 2019

# Adaptive Biotechnologies Corporation

By: /s/ Chad Cohen

Chad Cohen Chief Financial Officer

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# Adaptive Biotechnologies Enters Partnership with Illumina to Develop Distributable IVD Test Kits for clonoSEQ and immunoSEQ Dx

# Partnership Will Enable Physicians to Order Clinical Immunodiagnostic Testing that Can Be Performed in Local Laboratories

**SEATTLE, Wash., September 24, 2019** – Adaptive Biotechnologies Corporation (Nasdaq: ADPT), a commercial stage biotechnology company that aims to translate the genetics of the adaptive immune system into clinical products to diagnose and treat disease, today announced a partnership with Illumina, Inc. (Nasdaq: ILMN) to develop in-vitro diagnostic (IVD) test kits for Adaptive's current and future portfolio of next-generation sequencing (NGS)-based immunodiagnostics.

The test kits under development would expand the availability of Adaptive's clonoSEQ<sup>®</sup> Assay for assessing and monitoring minimal residual disease (MRD) for the management of patients with certain blood cancers and immunoSEQ Dx<sup>™</sup> Assay for pipeline applications. Clinicians currently order clonoSEQ to monitor MRD as a test performed at Adaptive's lab in Seattle. The planned IVD test kits will make it possible for hospitals and health systems to run Adaptive's clonoSEQ and immunoSEQ Dx assays in their local laboratories across the United States.

"We are proud to partner with Illumina to deliver on our promise to develop distributable kits for our novel immunodiagnostics to reach more patients," said Chad Robins, chief executive officer and co-founder of Adaptive Biotechnologies. "These IVD test kits will further validate Adaptive as a valued partner for standardized MRD monitoring and immune profiling solutions from research to the clinic."

Adaptive's immune medicine platform is uniquely suited for the development of standardized IVD test kits. Under the nonexclusive agreement, Adaptive will develop the clonoSEQ and immunoSEQ Dx IVD test kits to run on Illumina's NextSeq<sup>™</sup> 550Dx system. Adaptive will be responsible for obtaining necessary regulatory approvals for each IVD test kit and for their subsequent commercialization.

"By making Adaptive's clonoSEQ more accessible to patients, we are ensuring health care providers have access to a valuable part of a growing genomics ecosystem. Partnerships that bring exceptional clinical content to customers and patients represent an exciting opportunity in clinical genomics," said Dr. Phil Febbo, Chief Medical Officer of Illumina. "We are committed to unlocking the power of the genome through our work with Adaptive which will expand access to genomic-based testing in order to improve patient outcomes."

# About the clonoSEQ Assay

The clonoSEQ Assay was granted de novo designation and marketing authorization by FDA for the detection and monitoring of minimal residual disease (MRD) in patients with multiple myeloma (MM) and B-cell acute lymphoblastic leukemia (ALL) using DNA from bone marrow

samples. clonoSEQ is the first and only FDA-authorized *in vitro* diagnostic assay for MRD testing. It is also the first clinical diagnostic powered by immunosequencing to receive FDA clearance. clonoSEQ leverages Adaptive's proprietary immunosequencing platform to identify and quantify specific DNA sequences found in malignant cells, allowing clinicians to assess and monitor MRD during and after treatment. The assay provides standardized, accurate and sensitive measurement of MRD that allows physicians to predict patient outcomes, assess response to therapy over time, monitor patients during remission and detect potential relapse. Clinical practice guidelines in hematological malignancies recognize that MRD status is a reliable indicator of clinical outcomes and response to therapy, and clinical outcomes are strongly associated with MRD levels measured by the clonoSEQ Assay in patients diagnosed with ALL and MM. clonoSEQ testing is covered by Medicare and an expanding list of private payors in alignment with the FDA label.

clonoSEQ is a single-site assay performed at Adaptive Biotechnologies. It is also available as a CLIA-regulated laboratory developed test (LDT) service for use in other lymphoid cancers. For important information about the FDA-cleared uses of clonoSEQ, including the full intended use, limitations, and detailed performance characteristics, please visit www.clonoSEQ.com/technical-summary.

# **About Adaptive Biotechnologies**

Adaptive Biotechnologies is a commercial-stage biotechnology company focused on harnessing the inherent biology of the adaptive immune system to transform the diagnosis and treatment of disease. We believe the adaptive immune system is nature's most finely tuned diagnostic and therapeutic for most diseases, but the inability to decode it has prevented the medical community from fully leveraging its capabilities. Our proprietary immune medicine platform reveals and translates the massive genetics of the adaptive immune system with scale, precision and speed to develop products in life sciences research, clinical diagnostics, and drug discovery. We have two commercial products, and a robust clinical pipeline to diagnose, monitor and enable the treatment of diseases such as cancer, autoimmune conditions and infectious diseases. Our goal is to develop and commercialize immune-driven clinical products tailored to each individual patient. For more information, please visit <u>adaptivebiotech.com</u>.

# **Forward Looking Statements**

This press release contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements contained in this release other than statements of historical fact are forward-looking statements, including statements regarding Adaptive Biotechnologies' partnership with Illumina, ability to develop, commercialize and achieve market acceptance of our current and planned products and services, our research and development efforts, and other matters regarding our business strategies, use of capital, results of operations and financial position, and plans and objectives for future operations. In some cases, you can identify forward-looking statements by the words "may," "will," "expect," "plan," "believe," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks, uncertainties and other factors are described under "Risk Factors," "Management's Discussion and Analysis of

Financial Condition and Results of Operations" and elsewhere in the documents the Company files with the Securities and Exchange Commission (the "SEC") from time to time. We caution you that forward-looking statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. As a result, the forward-looking statements may not prove to be accurate. The forward-looking statements in this press release represent our views as of the date hereof. We undertake no obligation to update any forward-looking statements for any reason, except as required by law.

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# **INVESTOR CONTACT:**

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