# 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): June 27, 2007

# **EXACT SCIENCES CORPORATION**

(Exact Name of Registrant as Specified in its Charter)

#### **Delaware**

(State or Other Jurisdiction of Incorporation)

000-3217902-0478229(Commission File Number)(IRS Employer Identification No.)

**100 Campus Drive, Marlborough, Massachusetts** (Address of Principal Executive Offices)

**01752** (Zip Code)

Registrant's telephone number, including area code: (508) 683-1200

	Check the app	ropriate box	below if the	Form 8-1	K filing is	intended to	simultaneously	y satisfy	the filing (	obligation o	of the re	gistrant
under ar	ny of the follow	ing provision	ns ( <i>see</i> Ger	eral Instru	ection A.2	2. below):						

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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))

### Item 1.01 Entry into a Material Definitive Agreement.

On June 27, 2007, EXACT Sciences Corporation (the "Company") entered into a Second Amendment (the "Amendment") to that certain license agreement between the Company and Laboratory Corporation of America Holdings ("LabCorp") dated June 26, 2002, as amended (the "Agreement"). The Amendment modified LabCorp's exclusive rights to the Company's DNA technology for colorectal cancer screening to permit the Company to license its technology to select third-party organizations and commercial service laboratories, subject to LabCorp's preferential pricing terms, and to extend LabCorp's modified exclusive period under the Agreement until December 31, 2010. Additionally, the Amendment clarifies the rights and obligations with respect to the Company's Version 2 technology for colorectal cancer screening.

The Amendment also revised certain milestone and royalty obligations of LabCorp. The milestones were revised to eliminate milestone payments aggregating \$15 million based upon policy-level reimbursement approval from key payors including Medicare and inclusion of stool-based DNA screening in clinical practice guidelines. As revised under the Amendment, the Company may be eligible for up to an aggregate of \$40 million in milestone payments, all of which now relate to the achievement of significant sales thresholds. Royalties to the Company under the amended Agreement equal 15% of LabCorp's net revenues from tests performed using the Company's DNA technology licensed under the Agreement, and could increase to 17% if LabCorp achieves a significant annual net revenues threshold. LabCorp also retains preferential pricing terms over third-party organizations and commercial service laboratories to which the Company may license its DNA technology for colorectal cancer screening.

In addition, the Amendment eliminates approximately \$3 million in connection with certain historical third-party royalty amounts that the Company could have been required to pay LabCorp under certain conditions. Under the terms of the revised Agreement, the Company will potentially be obligated to reimburse LabCorp for certain third-party royalties, up to a maximum of \$1 million annually.

The Amendment provides LabCorp with termination rights if stool-based colorectal cancer screening is not included in clinical practice guidelines in the near term, if the Company's Version 2 technology is not commercially launched in the near term, or if the Company's Version 2 technology does not attain certain sensitivity and specificity thresholds in connection with technical validation.

The foregoing description of the Amendment is not complete and is qualified in its entirety by reference to the Amendment, which is filed as Exhibit 10.1 hereto and is incorporated herein by reference.

# Item 9.01 Financial Statements and Exhibits.

- (d) Exhibits:
  - \*\*10.1 Second Amendment to Agreement between EXACT Sciences Corporation and Laboratory Corporation of America Holdings, dated as of June 27, 2007

<sup>\*\*</sup> Confidential treatment has been requested for portions of this exhibit.

# **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 hereunto duly authorized.

**EXACT Sciences Corporation** 

July 3, 2007 By: /s/ Jeffrey R. Luber

Jeffrey R. Luber

Senior Vice President, Chief Financial

Officer, General Counsel, Treasurer, and Secretary

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# **EXHIBIT INDEX**

Exhibit Number Description

Second Amendment to Agreement between EXACT Sciences Corporation and Laboratory Corporation of America Holdings, dated as of June 27, 2007 10.1\*\*

\*\* Confidential treatment has been requested for portions of this exhibit.

# SECOND AMENDMENT TO AGREEMENT BETWEEN EXACT SCIENCES CORPORATION AND LABORATORY CORPORATION OF AMERICA HOLDINGS

This Second Amendment (this "Amendment") is made and effective as of June 27, 2007, by and between LABORATORY CORPORATION OF AMERICA HOLDINGS ("LabCorp") and EXACT SCIENCES CORPORATION ("EXACT").

WHEREAS, LabCorp and EXACT entered into an Agreement dated June 26, 2002, which was amended pursuant to a First Amendment dated January 19, 2004 (as amended, the "Agreement"); and

WHEREAS, the parties desire to amend certain provisions of the Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the parties agree to the following amendments to the Agreement, to be effective as of the date of execution of this Amendment:

- 1. <u>Extension of Exclusive Period</u>. Section 1.8 of the Agreement shall be deleted in its entirety and replaced with the following:
  - 1.8 "Exclusive Period" shall mean the period beginning on August 13, 2003 and ending on December 31, 2010, unless sooner terminated in accordance with Section 8.1, 11.2, 11.6, 11.7, 11.8, or 11.9.
- 2. <u>Approval for EXACT to use the Technology for Commercial Purposes</u>. Section 2.1(i) is hereby deleted in its entirety and replaced with the following:
  - (i) to use the Technology in-house for commercial purposes;
  - 3. Approval for EXACT to Grant Other Licenses.
  - a. LabCorp hereby approves EXACT licensing the Technology to the following entities and their affiliates for commercial purposes, as contemplated by Section 2.1(iv), and such entities shall be added to Schedule 2 of the Agreement: [\*\*\*\*\*\*\*\*]. LabCorp agrees that it will not unreasonably withhold approval with respect to other licenses EXACT wishes to grant pursuant to Section 2.1(iv) to entities that are not Designated Companies (as defined in Section 6.5). Any license granted by EXACT pursuant to Section 2.1(iv) shall not allow the licensee to transfer or sublicense the Technology.

- b. The following text is hereby deleted from Section 2.1 (iii): "... provided such license is [\*\*\*\*\*\*\*]."
- 4. <u>Launch of PV2 Test</u>.
  - a. A new Section 1.29 is hereby added to the Agreement as follows:
    - 1.29 "PV2" shall mean an Assay targeting genetic Loci that more specifically include [\*\*\*\*\*\*\*] and [\*\*\*\*\*\*\*].
  - b. The following text is hereby added to the end of Section 2.3:

EXACT expressly acknowledges that all rights of EXACT relating to PV2 are included within the Technology licensed under this Agreement, and EXACT agrees to use its best efforts to enable LabCorp to commercially launch PV2 by [\*\*\*\*\*\*\*\*].

- c. A new Section 3.6 is hereby added to the Agreement as follows:
  - On or before [\*\*\*\*\*\*\*\*], EXACT shall provide LabCorp with access to the data associated with [\*\*\*\*\*\*\*\*], and (iii) the overall sensitivity and specificity as a standalone dataset (the "PV2 Sample Data"), to attest the clinical sensitivity and specificity of PV2 claims stated in the following article: Steven H. Itzkowitz et al., *Improved Fecal DNA Test for Colorectal Cancer Screening*, 5 CLINICAL GASTROENTEROLOGY AND HEPATOLOGY 111 (2007). All such data provided to LabCorp pursuant to this provision shall be considered Confidential Information of EXACT. EXACT agrees that it will not unreasonably withhold approval for the PV2 Sample Data to be used by LabCorp to promote or describe PV2 in support of a PV2 commercial launch. Notwithstanding the foregoing, PV2 Sample Data that fails to meet the sensitivity/specificity targets described in Section 11.9 of this Amendment shall be treated as Confidential Information of EXACT.
- d. A new Section 3.7 is hereby added to the Agreement as follows:
  - 3.7 EXACT agrees to consult with LabCorp on [\*\*\*\*\*\*\*] (collectively, the "Collection [\*\*\*\*\*\*\*] Information"), as well as information known with respect to regulatory requirements. The Collection [\*\*\*\*\*\*\*] Information shall be treated as Confidential Information of EXACT.

#### 5. PV1 Capture Plates.

- a. A new Section 1.30 is hereby added to the Agreement as follows:
  - 1.30 "PV1" shall mean an Assay targeting genetic Loci that more specifically include [\*\*\*\*\*\*\*], as well as microsatellites [\*\*\*\*\*\*\*].
- b. A new Section 6.6 is hereby added to the Agreement as follows:
  - [\*\*\*\*\*\*\*] . EXACT agrees to reimburse LabCorp for all costs (reasonable out-of-pocket expenses) of LabCorp, its Affiliates and sublicensees associated with [\*\*\*\*\*\*\*] that are utilized for the performance of PV1 [\*\*\*\*\*\*\*] up to a maximum total cost of no more than [\*\*\*\*\*\*\*]. LabCorp will issue invoices to EXACT from time to time for reimbursement of such costs and EXACT agrees to pay all such invoices within thirty (30) days of the date of each invoice. In addition, LabCorp will retain such contractor(s) as necessary to provide LabCorp with training on how to conduct quality control with respect to the [\*\*\*\*\*\*\*\*], the costs of which will be reimbursed by EXACT within the [\*\*\*\*\*\*\*\*] limit. The terms of this Section 6.6 will terminate upon commercial launch of PV2 by LabCorp.

## 6. Royalty Rate.

- a. A new Section 1.31 is hereby added to the Agreement as follows:
  - 1.31 "Net Revenue" shall mean [\*\*\*\*\*\*\*] by LabCorp for the performance of Assays less the following deductions to the extent that they are applicable and are not already deducted in the [\*\*\*\*\*\*\*]: [\*\*\*\*\*\*\*\*] (up to maximum of [\*\*\*\*\*\*\*\*]) from clients/payors, based on the actual experience of LabCorp.
- b. A new Section 1.32 is hereby added to the Agreement as follows:
  - 1.32 "Annual Net Revenue" means the aggregate Net Revenues for an entire calendar year (except that, with respect to the 2007 calendar year only, Annual Net Revenue shall be deemed to only refer to the portion of the calendar year beginning on the date of the Second Amendment to this Agreement and ending on December 31, 2007).

- c. A new Section 1.33 is hereby added to the Agreement as follows:
  - 1.33 "Applicable Annual Percentage" means the percentage designated as the Applicable Annual Percentage in the chart below based on the corresponding Annual Net Revenue for the applicable calendar year:

Annual Net Revenue	Applicable Annual Percentage
\$0 to [*******]	15%
[*******] or greater	17%

- d. A new Section 1.34 is hereby added to the Agreement as follows:
  - 1.32 "Applicable Interim Percentage" means
  - (i) for the 2007 calendar year: 15%; and
  - (ii) for each calendar year thereafter: the percentage which was the Applicable Annual Percentage for the immediately preceding calendar year.
- e. Section 3.3.1 is hereby amended by being deleted in its entirety and replaced with the following:
  - 3.3.1 <u>Assays Performed and Net Revenue</u>. Within thirty (30) days following the end of each calendar month during the Term, LabCorp will notify EXACT in writing of: (i) the total number of Assays performed during the prior calendar month by LabCorp and its Affiliates and sublicensees, including Research Assays (separately reported), and (ii) the total Net Revenue of LabCorp and its Affiliates and sublicensees during the prior calendar month.
- f. Section 6.2.1 is hereby amended by being deleted in its entirety and replaced with the following:
- 6.2.1 Royalties.
  - (a) <u>Interim Monthly Royalties</u>. Within forty-five (45) days following the end of each calendar month during the Term, LabCorp agrees to pay EXACT a royalty equal to the Applicable Interim Percentage of its Net Revenue for that calendar month.
  - (b) <u>Annual Royalty True-up</u>. If the Applicable Annual Percentage for a calendar year is greater than the Applicable Interim Percentage

for that calendar year, then within sixty (60) days following the end of that calendar year, LabCorp agrees to pay EXACT a royalty equal to the difference between (i) the amounts previously paid that year (based on the Applicable Interim Percentage of its aggregate Net Revenue for each calendar month that calendar year), and (ii) the Applicable Annual Percentage of its Annual Net Revenue for that calendar year. If the Applicable Annual Percentage for a calendar year is less than the Applicable Interim Percentage for that calendar year, then LabCorp shall be entitled to a credit against future royalties payable under this Agreement in an amount equal to the difference between (a) the Applicable Annual Percentage of its Annual Net Revenue for that calendar year, and (b) the amounts previously paid that year (based on the Applicable Interim Percentage of its aggregate Net Revenue for each calendar month that calendar year).

Example 1: For example, if LabCorp's Annual Net Revenue during 2008 is [\*\*\*\*\*\*\*], then during 2009 LabCorp will pay 15% of its Net Revenue on a monthly basis. If, after the end of 2009, it is determined that LabCorp's Annual Net Revenue for 2009 is [\*\*\*\*\*\*\*] (which has a 17% corresponding Applicable Annual Percentage), then LabCorp would pay the difference between (i) 15% of its Annual Net Revenue for 2009 (which it has already paid), and (ii) 17% of its Annual Net Revenue for 2009 (which is the appropriate percentage based on that year's sales), as a "true-up."

Example 2: On the other hand, if LabCorp's Annual Net Revenue during 2008 is [\*\*\*\*\*\*\*], then during 2009 LabCorp will pay 17% of its Net Revenue on a monthly basis. If, after the end of 2009, it is determined that LabCorp's Annual Net Revenue for 2009 is [\*\*\*\*\*\*\*] (which has a 15% corresponding Applicable Annual Percentage), then LabCorp would receive a credit for the difference between (a) 15% of its Annual Net Revenue for 2009 (which is the appropriate percentage based on that year's sales), and (b) 17% of its Annual Net Revenue for 2009 (which it already overpaid).

g. All references in Section 6.2.2.a. of the Agreement to the "per-Assay fee" shall be deemed changed to references to the "royalty."

- h. Section 6.2.2.c. is hereby amended by being deleted in its entirety and replaced with the following:
  - c. Royalties On Existing Technology or Markers. If LABCORP is required to pay any third party, other than [\*\*\*\*\*\*\*\*] or its Affiliates, a royalty to use any of the protocols transferred by EXACT for PV1 as of the Commercial Launch Date pursuant to this Agreement (as such protocols are configured at the time of transfer by EXACT to LabCorp), or any of the loci in Schedule 5 (as Schedule 5 existed as of August 13, 2003), then the royalty due such third party shall be deducted from the Assay payments due under this Article 6.
- i. Except as provided in Section 6.7 (relating to [\*\*\*\*\*\*\*]), LabCorp agrees that it shall be solely responsible for any third party royalties due relating to PV2, to the extent relating to third party intellectual property identified and known to LabCorp as of the date of this Amendment. Intellectual property not identified and known to LabCorp as of the date of this Amendment will be handled in accordance with Section 6.2.2.d.
  - j. Section 2.2 is hereby amended by adding the following language to the end of the first sentence:
    - ..., subject to the royalty requirements set forth in 6.2.2.d.
  - k. Sections 1.3, 1.24, 3.3.2, 3.3.3, 6.2.2.b., 6.2.3, and Schedule 3 of the Agreement are hereby deleted.
- 1. The parties acknowledge that the rights and obligations of the parties under this Amendment were the result of good faith negotiations and represent an "equitable adjustment" to the terms of the Agreement pursuant to Section 6.2.2.d. based on the circumstances and intellectual property identified and known to LabCorp as of the date of this Amendment.
- 7. [\*\*\*\*\*\*\*] Payments .
  - a. A new Section 1.35 is hereby added to the Agreement as follows:
    - 1.35 "[\*\*\*\*\*\*] Agreement" means that Sublicense Agreement by and between LabCorp and [\*\*\*\*\*\*\*], whereby LabCorp licensed certain rights (the "[\*\*\*\*\*\*\*]") from [\*\*\*\*\*\*\*\*].
  - b. A new Section 1.36 is hereby added to the Agreement as follows:
    - 1.36 "[\*\*\*\*\*\*\*] Net Service Revenues" has the meaning of "Net Service Revenues" as defined in the [\*\*\*\*\*\*\*\*] Agreement.

- c. A new Section 1.37 is hereby added to the Agreement as follows:
  - 1.37 "[\*\*\*\*\*\*\*] Effective Royalty Rate" means the total amount (including but not limited to percentage royalties and minimum royalties) actually paid by LabCorp to [\*\*\*\*\*\*\*] during each Measuring Period of the Exclusive Period pursuant to the [\*\*\*\*\*\*\*] Agreement, divided by the [\*\*\*\*\*\*\*] Net Service Revenues from Assay sales during the same period.
- d. A new Section 1.38 is hereby added to the Agreement as follows:
  - 1.38 "[\*\*\*\*\*\*] Excess" shall mean the [\*\*\*\*\*\*\*] Effective Royalty Rate minus [\*\*\*\*\*\*\*].
- e. A new Section 1.39 is hereby added to the Agreement as follows:
  - 1.39 "Measuring Period" means each of the three following periods: (i) the portion of the 2007 calendar year beginning on the date of the Second Amendment to this Agreement and ending on December 31, 2007, combined with the entire 2008 calendar year; (ii) the 2009 calendar year; and (iii) the 2010 calendar year. With respect to the 2007 calendar year, a prorated portion of any minimum annual royalty payments made by LabCorp with respect to 2007 shall be attributed to the aforementioned portion of the calendar year for purposes of calculating the [\*\*\*\*\*\*\*] Effective Royalty Rate.
- f. A new Section 6.7 is hereby added to the Agreement as follows:
  - 6.7 In the event that, following a Measuring Period of the Exclusive Period, the [\*\*\*\*\*\*\*] Effective Royalty Rate is greater than [\*\*\*\*\*\*\*], then LabCorp will notify EXACT and EXACT will pay LabCorp an amount equal to the [\*\*\*\*\*\*\*] Excess times the [\*\*\*\*\*\*\*] Net Service Revenues, within 30 days after such notice.
- g. Exact recognizes that it has certain responsibilities as described in Section 9 of the First Amendment to the Agreement to reimburse LabCorp for certain [\*\*\*\*\*\*\*\*] royalty payments incurred over the term of the agreement. LabCorp is willing to exchange any claim for reimbursement from Exact in recognition of the value it is receiving in this Second Amendment to the parties' agreement, and, therefore, no amounts shall be payable by EXACT based on such section. Section 9 of the First Amendment to the Agreement is hereby deleted in its entirety.

- 8. Milestones.
- a. Milestone 4 (and the associated Milestone License Fee) on Schedule 4 of the Agreement shall be deemed eliminated for all purposes.
  - b. Milestone 5 on Schedule 4 of the Agreement is hereby deleted in its entirety and replaced with the following:

Upon LabCorp and its Affiliates' performance of [\*\*\*\*\*\*\*] in the aggregate, over the Term for third parties (excluding Research Assays).

- c. The Milestone License Fee for Milestone 5, as amended above, shall remain at [\*\*\*\*\*\*\*\*].
- d. Sections 1.16 and 11.6.2 of the Agreement are hereby deemed deleted in their entirety.
- 9. <u>Education and Awareness Efforts</u>. The following text is added to the end of Section 7.1 of the Agreement:

LabCorp agrees to issue joint press releases with EXACT concerning its entering into the Second Amendment to this Agreement with EXACT (the language of which shall be agreed upon and attached as Exhibit A to such Amendment) and the launch of PV2. The Parties agree to form a steering committee of at least four individuals (2 from LabCorp and 2 from EXACT) to meet regularly to discuss developments regarding the Assay, educational activities, commercially reasonable efforts to promote awareness of stoolbased DNA screening for colorectal cancer, or other issues related to this Agreement. Decisions regarding educational, promotional or advertising activities related to the Assay are in the sole discretion of LabCorp.

- 10. Rights of Termination.
  - a. A new Section 11.7 is hereby added to the Agreement as follows:
    - 11.7 This Agreement may be terminated by LabCorp upon written notice in the event stool-based colorectal cancer screening has not be accepted as a Standard of Care on or before [\*\*\*\*\*\*\*].
  - b. A new Section 11.8 is hereby added to the Agreement as follows:
    - 11.8 This Agreement may be terminated by LabCorp upon written notice in the event PV2 is not commercially

launched (meaning made generally available to LabCorp's customers) on or before [\*\*\*\*\*\*\*], provided the reason for delay in commercial launch can be attributed in whole or in part to EXACT. Without limiting the foregoing, the parties acknowledge that either of the following shall give rise to LabCorp's right to terminate the Agreement pursuant to this Section 11.8: (i) any failure of EXACT to provide all of the PV2 Sample Data described in Section 3.6 on or before [\*\*\*\*\*\*\*\*], or (ii) any failure of EXACT to fulfill its obligations with respect to [\*\*\*\*\*\*\*\*] on or before any of the deadlines to be mutually agreed upon by the parties in writing.

- c. A new Section 11.9 is hereby added to the Agreement as follows:
  - This Agreement may be terminated by LabCorp upon written notice in the event the PV2 Sample Data do not demonstrate sensitivity and specificity with a lower limit of the [\*\*\*\*\*\*\*] confidence interval of at least [\*\*\*\*\*\*\*\*] for each.
- 11. <u>Technology Exclusivity</u>.
  - a. Section 8.1 is hereby amended by being deleted in its entirety and replaced with the following:
    - 8.1 Exclusivity. EXACT may terminate the Exclusive Period and convert the license granted under Section 2.1 to a non-exclusive license for the remainder of Term immediately upon written notice to LABCORP in the event that LABCORP ceases to use EXACT as its sole licensor of DNA-based molecular diagnostics technology for the detection of colon and rectal cancer in stool at any time during the Exclusive Period. The Parties acknowledge that such right of conversion to a non-exclusive license shall not exist as a result of (i) any procurement, purchasing, marketing, sale or distribution by LABCORP of any commercially available diagnostic product approved by the FDA, or (ii) LABCORP's purchase of any components from any source for use in connection with performance of Assays.
- b. In Section 11.1, the words "with this Article 13" are hereby replaced with "with this Article 11", and the words "or Section 8.1" are hereby deleted.

# 12. [\*\*\*\*\*\*\*] Pricing.

Section 3.2 is hereby deleted in its entirety and replaced with the following:

- 13. Performance-Based License Fees. In Section 6.1.4, the date "[\*\*\*\*\*\*\*]" is hereby replaced with "[\*\*\*\*\*\*\*]."
- 14. Except as expressly modified herein, the Agreement and all of its terms and conditions shall continue in full force and effect.

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Amendment as of the date first above written.

### **Laboratory Corporation of America:**

### **EXACT Sciences Corporation:**

By: /s/ Bradford T. Smith

Bradford T. Smith Printed Name

Title: Executive Vice President

By: /s/ Don M. Hardison

Don M. Hardison Printed Name

Title: President and Chief Executive Officer