QUIDEL CORP /DE/ Form 8-K September 28, 2011

# 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 27, 2011

# **QUIDEL CORPORATION**

(Exact name of registrant as specified in its charter)

Delaware (State or Other Jurisdiction 0-10961 (Commission 94-2573850 (I.R.S. Employer

of Incorporation) File Number)

Identification No.)

10165 McKellar Court, San Diego, California 92121
(Address of Principal Executive Offices) (Zip Code)
Registrant s Telephone Number, Including Area Code: (858) 552-1100

Check the appropriate	box below if the Form	8-K is intended to	simultaneously s	satisfy the filing	obligation of the	e registrant under a	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))

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

On September 27, 2011, Quidel Corporation (the <u>Company</u>) entered into the Second Amendment (the <u>Amendment</u>) to Quidel/Inverness Settlement Agreement dated April 27, 2005 (the <u>Agreement</u>), as amended by an Addendum dated June 19, 2006, with Alere Inc. (formerly known as Inverness Medical Innovations, Inc.) (<u>Alere</u>).

The Amendment, which is effective as of April 1, 2011, amends certain royalty and other provisions in the Agreement and enables the Company to buy-down and buy-out its future royalty obligation under the Agreement for payments totaling \$29.5 million. As described in more detail below, under the Amendment, the Company will make an initial cash payment of \$13.8 million to Alere in connection with a buy-down of the Company s royalty obligations for the period beginning July 1, 2011. In addition, the Company expects to exercise its buy-out right for any remaining future royalty obligation by exercising the Royalty Termination Option (as described below) in January 2012, thereby terminating the Company s obligation to pay future royalties under the Agreement in exchange for a fixed cash payment in the amount of \$15.7 million less the sum of specified third and fourth quarter 2011 royalties, resulting in the Company receiving a fully paid up license effective January 1, 2012.

More specifically, the Amendment provides, among other matters, that the Company and its Affiliates (as defined in the Agreement) will pay Alere a royalty on all Adjusted Quidel Product Sales (as defined in the Amendment) as follows:

- (1) in partial fulfillment and as a buy-down of the Company s total royalty obligations for the period beginning July 1, 2011 and ending with the expiration of the last patent to expire of the Inverness Portfolio of Lateral Flow Patents (as defined in the Agreement), the Company will pay Alere the sum of \$13,800,000 within five days of the Signature Date;
- (2) for the period beginning July 1, 2011 and ending September 30, 2011, a royalty of 4.25% (the O3 2011 Royalty) to be paid no later than December 29, 2011;
- (3) for the period beginning October 1, 2011 and ending December 31, 2011, a royalty of 4.25% (the <u>Q4 2011 Royalty</u>) to be paid by the earlier of (a) March 30, 2012 or (b) if the Royalty Termination Option (as described below) is exercised thirty days from the Option Notice Date (as defined in the Amendment); and
- (4) for the period beginning January 1, 2012, either a royalty of 4.25% in each calendar quarter, payable within ninety days of the end of the calendar quarter, or if the Royalty Termination Option is exercised, a payment of \$15,700,000 less the sum of the Q3 2011 Royalty and the Q4 2011 Royalty (the Royalty Termination Payment) within thirty days from the Option Notice Date.

The Royalty Termination Option permits either party, in its sole discretion, to exercise such Option and trigger the Company s obligation to pay the Royalty Termination Payment by written notice given not earlier than January 1, 2012 or later than January 30, 2012. Upon receipt by Alere of the Royalty Termination Payment (subject to Alere s right to audit prior periods), the sole effect of the Royalty Termination Option is that the license granted to the Company under the Agreement shall become a fully paid up license effective January 1, 2012, with the Company no longer having future royalty obligations under the Agreement, subject to certain exceptions relating to future acquisitions of the Company or dispositions of a product line.

In addition, the Amendment revises certain provisions relating to a Change in Control (as defined in the Agreement) and provides, among other matters, that in the event a third party assumes control of the Company pursuant to a Change of Control, the license granted to the Company and its Affiliates will continue to apply to Quidel Products (as defined in the Agreement), provided that the third party acquirer will agree in writing to be bound by the terms of the Agreement, as amended by the Amendment, including any remaining royalty obligations under the Agreement, as amended, for sales of Quidel Royalty Bearing Products. The Amendment further provides that, in the event of a Change of Control whereby a third party already participating in the diagnostics market in one or more of the jurisdictions in which Alere has effective patents assumes control of the Company, the royalty rate, if any, due under the Agreement shall increase by 25% (from 4.25% to 5.3125%), provided that no such increased royalties nor any other royalty obligation shall be owed if the Royalty Termination Option is exercised, as all royalty obligations of the Company under the Agreement shall be deemed fully paid as set forth in the Agreement upon such exercise.

The foregoing description of the Amendment is qualified in its entirety by reference to the Amendment, a copy of which is attached as Exhibit 10.1 and incorporated by reference in its entirety in this Item 1.01.

This Form 8-K contains forward-looking statements within the meaning of the federal securities laws that involve material risks, assumptions and uncertainties. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those that may be described or implied in the forward-looking statements. As such, no forward-looking statement can be guaranteed. Differences in actual results and performance may arise as a result of a number of factors including, without limitation, seasonality, the timing of onset, length and severity of cold and flu seasons, the level of success in executing on our strategic initiatives, our reliance on sales of our influenza diagnostic tests, uncertainty surrounding the detection of novel influenza viruses involving human specimens, our ability to develop new products and technology, adverse changes in the competitive and economic conditions in domestic and international markets, our reliance on and actions of our major distributors, technological changes and uncertainty with research and technology development, including any molecular-based technology, the medical reimbursement system currently in place and future changes to that system, manufacturing and production delays or difficulties, adverse actions or delays in product reviews by the U.S. Food and Drug Administration (the FDA), our ability to comply with FDA, environmental and other regulations, our ability to meet unexpected increases in demand for our products, our ability to execute our strategy, including the integration of new companies or technologies, disruptions in the global capital and credit markets, our ability to hire key personnel, intellectual property, product liability, environmental or other litigation, potential required patent license fee payments not currently reflected in our costs, adverse changes in our international markets, potential inadequacy of booked reserves and possible impairment of goodwill, and lower-than-anticipated acceptance, sales or market penetration of our new products. Forward-looking statements typically are identified by the use of terms such as may, will, might, estimate, and similar words, although some forward-looking statements are expressed differently. The risks described under Risk Factors in reports and registration statements that we file with the SEC from time to time should be carefully considered. You are cautioned not to place undue reliance on these forward-looking statements, which reflect management s analysis only as of the date of this Form 8-K. We undertake no obligation to publicly release the results of any revision or update of the forward-looking statements, except as required by law.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit Number Description of Exhibit

10.1 Second Amendment to Quidel/Inverness Settlement Agreement dated September 27, 2011

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 28, 2011

#### QUIDEL CORPORATION

By: /s/ Robert J. Bujarski Name: Robert J. Bujarski

Its: SVP, General Counsel & Corporate Secretary

#### **EXHIBIT INDEX**

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