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QIAGEN NV Form 6-K April 28, 2011 Table of Contents

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 6-K

**Report of Foreign Private Issuer** 

**Pursuant to Rule 13a-16 or 15d-16** 

under the Securities Exchange Act of 1934

For the quarterly period ended March 31, 2011

Commission File Number 0-28564

# QIAGEN N.V.

(Translation of registrant s name into English)

Spoorstraat 50

# Edgar Filing: QIAGEN NV - Form 6-K

# 5911 KJ Venlo

# The Netherlands

(Address of principal executive office)

# QIAGEN N.V.

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#### OTHER INFORMATION

On April 27, 2011, QIAGEN N.V. (Nasdaq: QGEN; Frankfurt, Prime Standard: QIA) issued a press release announcing its unaudited financial results for the quarter ended March 31, 2011. The press release is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

QIAGEN has regularly reported adjusted results, which are considered non-GAAP financial measures, to give additional insight into our financial performance as a supplement to understand, manage, and evaluate our business results and make operating decisions. Adjusted results should be considered in addition to the reported results prepared in accordance with U.S. generally accepted accounting principles, but should not be considered as a substitute. Reconciliations of reported results to adjusted results are included in the tables accompanying the press release. We believe certain items should be excluded from adjusted results when they are outside of our ongoing core operations, vary significantly from period to period, or affect the comparability of results with the Company s competitors and our own prior periods.

The non-GAAP financial measures used in this press release are non-GAAP operating income, pre-tax income, net income and diluted earnings per share. These adjusted results exclude costs related to amortization of acquired intangible assets, impairment losses, share-based payment expenses, acquisition, integration and restructuring expenses, including inventory fair value adjustments related to business acquisitions, as well as non-recurring charges or income. Management views these costs as not indicative of the profitability or cash flows of our ongoing or future operations and therefore considers the adjusted results as a supplement, and to be viewed in conjunction with, the reported GAAP results.

We also consider results on a constant currency basis. Our functional currency is the U.S. dollar and our subsidiaries functional currencies are the local currency of the respective countries in which they are headquartered. A significant portion of our revenues and expenses is denominated in euros and currencies other than the United States dollar. Management believes that analysis of constant currency period-over-period changes is useful because changes in exchange rates can affect the growth rate of net sales and expenses, potentially to a significant degree. Constant currency figures are calculated by translating the local currency actual results in the current period using the average exchange rates from the previous year s respective period instead of the current period.

We use non-GAAP and constant currency financial measures internally in our planning, forecasting and reporting, as well as to measure and compensate our employees. We also use the adjusted results when comparing to our historical operating results, which have consistently been presented on an adjusted basis.

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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.

QIAGEN N.V.

By: /s/ Roland Sackers Roland Sackers Chief Financial Officer

Date: April 28, 2011

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#### EXHIBIT INDEX

Exhibit No. Exhibit

99.1 Press Release dated April 27, 2011

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Exhibit 99.1

#### **QIAGEN Reports First Quarter 2011 Results**

Net sales of \$264.3 million (0%, -2% CER) reflect anticipated soft start to 2011, disruptions in Japan and other markets reduce growth by ~2 percentage points

Adjusted EPS rises to \$0.21 (+5%) on productivity initiatives that support investments to drive innovation and growth; free cash flow more than doubles to \$29.0 million

New pharma co-development agreements reached, expanding Personalized Healthcare beyond oncology; U.S. submission of KRAS cancer biomarker advances

Global rollout of QIAsymphony RGQ automated platform progressing well

Proposed acquisition of Cellestis to provide novel pre-molecular disease detection technology that highly complements DNA- and RNA-based molecular diagnostics

QIAGEN reaffirms expectations: Adjusted earnings expected to grow faster than net sales in 2011, focus on expansion to further accelerate growth in 2012

**Venlo, The Netherlands, April 27, 2011** QIAGEN N.V. (NASDAQ: QGEN; Frankfurt Prime Standard: QIA) today announced results of operations for the first quarter of 2011. Net sales of \$264.3 million were largely unchanged compared to the first quarter of 2010 (-2% at constant exchange rates, or CER), while adjusted earnings per share rose 5% to \$0.21 (\$0.20 CER) and free cash flow more than doubled to \$29.0 million from \$12.3 million in the first quarter of 2010.

Results in the 2011 first quarter were unexpectedly affected by disruptions in Japan, Australia/New Zealand and northern Africa, which reduced net sales by approximately two percentage points.

We remain on track to deliver on our full-year growth targets despite the expected softness in the first quarter, which was exacerbated by several factors including the crisis in Japan. As we position ourselves for sequentially increasing growth, we are making broad progress to expand our business. The initiatives we have put in place are set to drive the improving performance during the course of 2011 and position us to further accelerate growth in 2012, said Peer Schatz, Chief Executive Officer of QIAGEN N.V.

Several milestones in the first quarter of 2011 show QIAGEN is executing well on a strategic plan to expand the molecular content available on automated platforms. The rollout of QIAsymphony RGQ continues to progress well, and customer feedback is validating the goal of this novel platform to drive dissemination of molecular diagnostics. Our recent proposal to acquire Cellestis is expected to add a novel pre-molecular technology and commercial assays that can be migrated to our automated platforms and highly complements our DNA- and RNA-based molecular diagnostics portfolio. In addition, we are expanding our portfolio of companion diagnostic partnerships in oncology and other indications. One of the new co-development agreements signed in the first quarter with a major pharmaceutical company added an additional, new and very large therapeutic area. The U.S. regulatory submission of the KRAS biomarker for use as a companion diagnostic is advancing toward completion. QIAGEN is well positioned to achieve the goals set for 2011 and deliver growth in the future at a faster pace.

#### First Quarter 2011 Results

in \$ millions, except per share information	Q1 2011	Q1 2010	Change
Net sales	264.3	264.4	0%
Operating income, adjusted	70.5	73.6	-4%
Net income, adjusted	49.5	49.3	0%
EPS, adjusted (\$)	0.21	0.20	

For information on the adjusted figures, please refer to the reconciliation table accompanying this release.

Net sales were largely unchanged at \$264.3 million in the first quarter of 2011 compared with \$264.4 million in the first quarter of 2010, but declined 2% CER. Operating income of \$38.4 million declined 14% from \$44.7 million in the 2010 quarter. Net income fell 15% to \$28.0 million in the 2011 quarter from \$33.0 million in the year-ago quarter, while diluted earnings per share were \$0.12 (based on 240.4 million diluted shares) in the 2011 quarter compared to \$0.14 in the same 2010 quarter (based on 241.9 million diluted shares).

Adjusted operating income in the first quarter of 2011 declined 4% to \$70.5 million from \$73.6 million in the same 2010 quarter, with an adjusted operating income margin of 27% of net sales compared to 28% in the same 2010 quarter. Adjusted net income was largely unchanged at \$49.5 million in the 2011 quarter compared to \$49.3 million in the same quarter of 2010. Adjusted diluted earnings per share rose to \$0.21 in the 2011 quarter from \$0.20 in the first quarter of 2010.

Reconciliations of reported results in accordance with U.S. generally accepted accounting principles (GAAP) to adjusted results are included in the tables accompanying this release.

Our first-quarter results are not indicative of the full-year performance we are targeting. We expect to deliver substantially higher growth rates as the year progresses, with the strongest results anticipated in the second half of 2011 as we expect to benefit from the rollout of QIAsymphony RGQ, geographic expansion and predictions for improving market conditions, said Roland Sackers, Chief Financial Officer of QIAGEN N.V. Adjusted earnings during 2011 should grow at a faster pace than net sales due to operational excellence initiatives. Our strong financial position also provides resources to fund the acquisition of Cellestis while maintaining strategic flexibility to strengthen our businesses through sustained R&D investments and additional targeted acquisitions.

#### **Business Review**

Performance during the first quarter of 2011 was soft across the four customer classes as net sales were largely unchanged, but declined 2% CER compared to the year-ago period. The first quarter of 2010 had benefited from the contributions of exceptionally strong instrument sales and solid demand for HPV screening tests in the U.S., which then declined sharply during the rest of 2010 due to a reduction in patient visits to physicians, linked to weak economic conditions. Additionally, product deliveries in the first quarter of 2011 were disrupted by natural disasters in Japan and Australia/New Zealand and political unrest in Egypt, where QIAGEN is a major supplier to the hepatitis C testing programs, reducing net sales by approximately two percentage points.

Among product categories, consumables and related revenues provided 87% of sales in the first quarter of 2011, declining 1% CER from the same 2010 period. Instrumentation contributed 13% of sales and fell 9% CER compared to exceptionally strong year-ago results, when net sales rose 37% CER.

Among the regions, the Americas (47% of sales) delivered 1% CER growth in net sales compared to the first quarter of 2010, while Europe / Middle East / Africa (35% of sales) declined 1% CER and Asia-Pacific/Japan (18% of sales) fell 10% CER.

Molecular Diagnostics (44% of net sales) declined 2% CER from the first quarter of 2010 as Profiling and Prevention offset gains in Personalized Healthcare, which grew on expansion of companion diagnostic sales in Europe and co-development projects with pharmaceutical companies. Profiling (infectious disease testing) was adversely affected by sales disruptions in Japan and Egypt. Prevention was hampered by soft sales of HPV tests in the U.S. However, trends are becoming more positive in the U.S., providing further support for expectations of improving sales in the coming quarters. Changes of trends in patient visits to physicians are typically reflected in sales with a delay of a few months.

**Applied Testing** (6% of net sales) faced a challenging year-over-year comparison as net sales in the first quarter of 2011 fell 13% CER from the same 2010 period, which included exceptionally strong sales of instruments and overshadowed growth in consumables. Long-term trends in this customer class, which can have volatile quarterly results, are supported by expansion in human identification, veterinary testing and food safety.

**Pharma** (21% of net sales) benefited from sustained demand for advanced molecular technologies supporting R&D initiatives for new medicines, particularly gene-based drug development activities. Net sales in the first quarter of 2011 rose 2% CER compared to the same period in 2010.

**Academia** (29% of net sales) saw cautious purchasing patterns for consumable kits and instruments in some key markets during the first quarter of 2011, as net sales declined 2% CER compared to the same period in 2010.

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#### **Expanding in 2011 to Further Accelerate Growth in 2012**

QIAGEN continues to make progress on strategic initiatives to leverage its global leadership in Sample & Assay Technologies and strengthen its position in all customer classes. A key focus is expanding the offering of molecular content for use on various automated platforms, driven by both internal R&D efforts as well as targeted acquisitions.

Important to this strategy is the global rollout of QIAsymphony RGQ, a next-generation automated modular testing platform that addresses customer demands for a versatile mid-throughput system. Since the launch of the first modular unit (QIAsymphony SP) in 2008, more than 400 systems have been placed around the world. The late 2010 launch of QIAsymphony RGQ, which incorporates the Rotor-Gene Q (RGQ) real-time PCR detection platform, is expected to accelerate placements, particularly in Molecular Diagnostics. QIAsymphony RGQ is the first modular system that automates entire laboratory workflows from initial sample preparation to final result, and allows customers to run commercial assays as well as to develop and conduct their own tests.

Customer response has been very positive to QIAsymphony RGQ, with an increasing number of system placements achieved in the first quarter of 2011 for customer evaluation and validation. QIAGEN expects to significantly increase the number of system placements during 2011 and 2012, which will help to accelerate growth in the coming years.

QIAGEN also has made progress on a series of initiatives to add molecular content particularly in Molecular Diagnostics to QIAsymphony RGQ as well as other automated platforms, which include the next-generation QIAensemble system in development and point of need testing platforms. More than 20 new products were launched in the first quarter of 2011, while nearly 40 regulatory clearances or approvals were received from agencies around the world.

In an important strategic move in early April, QIAGEN announced an agreement to acquire Cellestis Limited (CST:AU) for approximately A\$341 million (US\$355 million) in cash, providing access to the QuantiFERON® technology that offers a new dimension in disease detection not currently possible with other diagnostic methods. Cellestis has commercialized this technology, which tests whole blood samples for the presence of systemically amplified molecular analytes that provide information from the immune system s memory, in tests for latent tuberculosis (TB) and the life-threatening cytomegalovirus (CMV). Following completion of the transaction, which is expected in mid-2011, QIAGEN plans to migrate QuantiFERON® products onto its automated platforms and develop tests that complement QIAGEN s DNA- and RNA-based molecular diagnostics portfolio. QIAGEN is considering other targeted acquisitions in line with its focused, consistent and value-creating strategy.

In Personalized Healthcare, QIAGEN is actively expanding its portfolio of co-development projects with leading pharmaceutical and biopharmaceutical companies. Among the new projects is an agreement reached in the first quarter of 2011 with an undisclosed major pharmaceutical company that added a new and very large therapeutic area for companion diagnostics. Negotiations are progressing with other companies on co-development projects, both in oncology as well as in areas including central nervous system, cardiovascular and other diseases. QIAGEN is positioned as a global leader in Personalized Healthcare with more than 15 projects under way to develop companion diagnostics. These tests provide information to guide treatment decisions, particularly in cancer patients. In the U.S., the modular submission of the therascreen KRAS assay, which

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determines the gene mutation status in patients with metastatic colorectal cancer, remains on track for completion in the first half of 2011.

In Prevention, momentum is building toward the adoption of molecular diagnostics for use in screening women at risk of the human papillomavirus (HPV), a cause of cervical cancer. In the first quarter of 2011, progress was made toward adoption of HPV testing in almost 10 countries where major pilot projects are expected to begin in 2011. In the U.S., QIAGEN continues to demonstrate success in its market conversion initiatives, which are being targeted at integrated healthcare networks and large physician groups. QIAGEN continues to expect higher sales of HPV tests in 2011 based on further conversion of the U.S. market, while also taking into account factors driven by the anticipated entry of competitors during the second half of 2011.

#### 2011 outlook

#### (Barring unforeseen events)

QIAGEN reaffirms its expectations to deliver adjusted earnings growth at a faster pace than net sales. Full-year net sales in 2011 are expected to rise approximately 5-7% CER, reflecting organic growth and no meaningful contributions from acquisitions completed in 2010. Adjusted earnings per share are expected to grow approximately 7-13% CER. Results are expected to move toward substantially higher growth rates during the course of 2011. These expectations do not take into account the acquisition of Cellestis (expected to be completed in mid-2011) or other potential acquisitions that could be completed during the year, and an improving economic environment, which could provide additional growth contributions. These expectations also do not take into account any potential supply disruptions in Japan and northern Africa during the rest of 2011.

#### **Conference Call and Webcast Details**

Information on QIAGEN s business and financial performance will be presented during a conference call on Thursday, April 28, 2011, at 9:30 ET / 15:30 CET. The corresponding presentation slides will be available for download shortly before the conference call at <a href="https://www.qiagen.com/goto/ConferenceCall">www.qiagen.com/goto/ConferenceCall</a>, and a webcast is available at this website. A replay will also be made available on this website.

#### **Use of Adjusted Results**

QIAGEN has regularly reported adjusted results, as well as results considered on a constant exchange rate basis, to give additional insight into its financial performance. Adjusted results should be considered in addition to the reported results prepared in accordance with generally accepted accounting principles, but should not be considered as a substitute. QIAGEN believes certain items should be excluded from adjusted results when they are outside of its ongoing core operations, vary significantly from period to period, or affect the comparability of results with the company s competitors and its own prior periods. Reconciliations of reported results to adjusted results are included in the tables accompanying this release. QIAGEN is also reporting free cash flow results which are calculated as net cash provided by operating activities less capital expenditures for the purchase of property, plant and equipment.

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#### **About QIAGEN**

QIAGEN N.V., a Netherlands holding company, is the leading global provider of Sample & Assay technologies. Sample technologies are used to isolate and process DNA, RNA and proteins from biological samples such as blood or tissue. Assay technologies are used to make these isolated biomolecules visible. QIAGEN has developed and markets more than 500 sample and assay products as well as automated solutions for such consumables. QIAGEN provides its products to molecular diagnostics laboratories, academic researchers, pharmaceutical and biotechnology companies, and applied testing customers for purposes such as forensics, animal or food testing and pharmaceutical process control. QIAGEN s assay technologies include one of the broadest panels of molecular diagnostic tests available worldwide. This panel includes the first FDA-approved test for human papillomavirus (HPV), the primary cause of cervical cancer. QIAGEN employs nearly 3,600 people in over 30 locations worldwide. Further information about QIAGEN can be found at http://www.qiagen.com/.

Certain of the statements contained in this news release may be considered forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended. To the extent that any of the statements contained herein relating to QIAGEN s products, markets, strategy or operating results, including without limitation its expected operating results, are forward-looking, such statements are based on current expectations and assumptions that involve a number of uncertainties and risks. Such uncertainties and risks include, but are not limited to, risks associated with management of growth and international operations (including the effects of currency fluctuations, regulatory processes and dependence on logistics), variability of operating results and allocations between business segments, the commercial development of markets for our products in applied testing, personalized healthcare, clinical research, proteomics, women s health/HPV testing and nucleic acid-based molecular diagnostics; changing relationships with customers, suppliers and strategic partners; competition; rapid or unexpected changes in technologies; fluctuations in demand for QIAGEN s products (including fluctuations due to general economic conditions, the level and timing of customers funding, budgets and other factors); our ability to obtain regulatory approval of our products; difficulties in successfully adapting QIAGEN s products to integrated solutions and producing such products; the ability of QIAGEN to identify and develop new products and to differentiate and protect our products from competitors products; market acceptance of QIAGEN s new products and the integration of acquired technologies and businesses. For further information, please refer to the discussions in reports that QIAGEN has filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC).

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#### **Contacts:**

**Investor Relations** 

Dr. Solveigh Mähler Albert F. Fleury e-mail: ir@qiagen.com +49 2103 29 11710

+1 301 944 7028

**Public Relations** 

Dr. Thomas Theuringer

+49 2103 29 11826

e-mail: pr@qiagen.com

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# QIAGEN N.V.

# CONDENSED CONSOLIDATED STATEMENTS OF INCOME

# (unaudited)

(in \$ thousands, except per share data)	Three months ended March 31,		
(III & III) Usunds, except per siture data)	2011	2010	
Net sales	264,265	264,364	
Cost of sales	92,117	91,152	
Gross profit	172,148	173,212	
Operating expenses:			
Research and development	32,667	31,597	
Sales and marketing	68,414	64,436	
General and administrative, integration and other	26,397	26,340	
Acquisition-related intangible amortization	6,225	6,158	
Total operating expenses	133,703	128,531	
Income from operations	38,445	44,681	
Other income (expense):			
Interest income	1,271	689	
Interest expense	(6,307)	(6,254)	
Other income, net	1,878	2,235	
Total other expense	(3,158)	(3,330)	
Income before provision for income taxes	35,287	41,351	
Provision for income taxes	7,306	8,337	
Net income	27,981	33,014	
Weighted average number of diluted common shares	240,382	241,924	
Diluted net income per common share	\$ 0.12	\$ 0.14	
Diluted net income per common share, adjusted	\$ 0.21	\$ 0.20	

# QIAGEN N.V.

# CONDENSED CONSOLIDATED BALANCE SHEETS

(in \$ thousands, except par value)	March 31, 2011 (unaudited)	December 31, 2010
Assets		
Current Assets:		
Cash and cash equivalents	776,581	828,407
Short-term investments	162,346	106,077
Accounts receivable, net	202,215	197,418
Income taxes receivable	12,647	10,920
Inventories, net	132,752	126,633
Prepaid expenses and other	76,624	64,402
Deferred income taxes	25,094	30,731
Deterred meonic taxes	25,094	30,731
Total current assets	1,388,259	1,364,588
Long-Term Assets:		
Property, plant and equipment, net	369,955	345,664
Goodwill	1,364,183	1,352,281
Intangible assets, net	752,541	753,327
Deferred income taxes	31,045	37,182
Other assets	52,072	60,953
Chief disets	32,072	00,733
Total long-term assets	2,569,796	2,549,407
Total assets	3,958,055	3,913,995
Liabilities and Shareholders Equity		
Current Liabilities:		
Accounts payable	51,976	47,803
Accrued and other liabilities	197,951	209,054
Income taxes payable	17,821	25,211
Current portion of long-term debt	76,332	75,835
Deferred income taxes	30,809	30,504
	·	·
Total current liabilities	374,889	388,407
Long-Term Liabilities:		
Long-term debt, net of current portion	796,865	797,171
Deferred income taxes	191,160	200,667
Other liabilities		51,397
Ouici naomues	58,846	31,397
Total long-term liabilities	1,046,871	1,049,235
Shareholders Equity:		
Common shares, EUR .01 par value:		
Authorized - 410,000 shares		
Issued and outstanding - 233,683 shares in 2011 and 233,115 shares in 2010	2,732	2,724
assuce and outstanding - 255,005 shares in 2011 and 255,115 shares in 2010	2,132	2,124

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Additional paid-in capital	1,659,073	1,648,985
Retained earnings	787,871	759,890
Accumulated other comprehensive income	86,619	64,754
Total shareholders equity	2,536,295	2,476,353
Total liabilities and shareholders equity	3,958,055	3,913,995

#### QIAGEN N.V.

#### RECONCILIATION OF REPORTED TO ADJUSTED FIGURES

(unaudited)

Three months ended March 31, 2011

(in \$ millions, except EPS data)

	Net Sales	Gross Profit	Operating Income	Pre-tax Income	Income Tax	Net Income	Diluted EPS*
Reported results	264.3	172.1	38.4	35.3	(7.3)	28.0	\$ 0.12
Adjustments:							
Business integration, acquisition related and restructuring							
costs		0.1	3.2	3.3	(1.1)	2.2	0.01
Purchased intangibles amortization		16.8	23.0	23.0	(7.8)	15.2	0.06
Share-based compensation		0.3	4.0	4.0	(0.8)	3.2	0.01
Other non-recurring income and expense		1.6	1.9	1.3	(0.4)	0.9	0.01
Total adjustments		18.8	32.1	31.6	(10.1)	21.5	0.09
Adjusted results	264.3	190.9	70.5	66.9	(17.4)	49.5	\$ 0.21

Three months ended March 31, 2010

(in \$ millions, except EPS data)

			Operating	Pre-tax			Diluted
	Net Sales	Gross Profit	Income	Income	Income Tax	Net Income	EPS*
Reported results	264.4	173.2	44.7	41.3	(8.3)	33.0	\$ 0.14
Adjustments:							
Business integration, acquisition related and restructuring							
costs		0.8	5.1	5.1	(1.7)	3.4	0.01
Purchased intangibles amortization		15.1	21.2	21.2	(10.2)	11.0	0.04
Share-based compensation		0.1	2.6	2.6	(0.7)	1.9	0.01
Total adjustments		16.0	28.9	28.9	(12.6)	16.3	0.06
Adjusted results	264.4	189.2	73.6	70.2	(20.9)	49.3	\$ 0.20

<sup>\*</sup> Using 241.9 M diluted shares

<sup>\*</sup> Using 240.4 M diluted shares