

QUIDEL CORP /DE/  
Form 424B3  
October 24, 2001

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PROSPECTUS

## QUIDEL CORPORATION

### 2,486,514 Shares of Common Stock of Quidel Corporation

This prospectus relates to 2,486,514 shares of our common stock that may be sold from time to time by the selling stockholders named in this prospectus.

Our common stock trades on the Nasdaq National Market under the symbol "QDEL." On October 23, 2001, the closing sale price for the common stock was \$6.49.

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**These securities are speculative and involve risks. You should carefully consider the factors specified under the caption "Risk Factors" commencing on page 3 of this prospectus.**

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**These securities have not been approved or disapproved by the Securities and Exchange Commission or any state securities commission. Neither the Securities and Exchange Commission nor any state securities commission has passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.**

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**The date of this prospectus is October 24, 2001**

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## QUIDEL CORPORATION

We are a worldwide leader in developing, manufacturing and marketing point-of-care rapid diagnostic tests for the detection and management of a variety of medical conditions and illnesses. This leadership position includes a 58%, 40% and 20% market share in Pregnancy, Strep A and Influenza products, respectively. These products provide health care professionals and consumers with accurate and cost-effective diagnostic information at the point-of-care. We sell our products to professionals for use in physician's offices, hospitals, clinical laboratories, and wellness screening centers. We also manufacture a line of products that we sell to consumers through distribution partners and organizations that provide store branded products. We focus our products substantially on women and family health in areas such as reproduction, infectious diseases, general health screening and diseases associated with the elderly.

We commenced our operations in 1979 and launched our first products, dipstick-based pregnancy tests, in 1984. Our product base has expanded through internal development and acquisitions of other products. Our product areas are pregnancy and ovulation, infectious disease, autoimmune diseases, osteoporosis and urinalysis, for professional, research and home use.

We market our products in the United States of America through a network of national and regional distributors, supported by a direct sales force. In Europe and the rest of the world, we sell and market from regionally based subsidiaries in the United Kingdom, Italy and Germany and through sales representation in Australia (encompassing the Pacific Rim) and Latin America and other international locations by channeling products through distributor organizations and sales agents.

Because we changed our fiscal year in August 1999 from a March 31 year-end to a December 31 year-end, we sometimes refer in this document to the year ended December 31, 2000 as "fiscal 2000" but we refer to the year ended December 31, 1999 as "calendar 1999."

Our executive offices are located at 10165 McKellar Court, San Diego, California 92121, and our telephone number is (858) 552-1100.

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## RISK FACTORS

**Our operating results may fluctuate as a result of factors which are outside our control, and this could have a negative effect on the price of our common stock.**

Fluctuations in our operating results, for any reason, that decrease sales or profitability could cause our growth or operating results to fall below the expectations of investors and securities analysts, and this could cause our stock price to decline. The market price of our common stock has fluctuated substantially in the past. Between June 30, 2000 and June 30, 2001, the price of our common stock, as reported on the Nasdaq National Market, has ranged from a low of \$3.00 to a high of \$7.25. We expect the market price of our common stock to continue to experience significant fluctuations in the future in response to a variety of factors, including fluctuation in our operating results.

For the six months ended June 30, 2001, revenues decreased \$3.1 million to \$35.1 million from \$38.2 million for the six months ended June 30, 2000. We had income before income taxes of \$0.3 million for the six months ended June 30, 2001 compared to income before income taxes and certain nonrecurring items of \$1.7 million for the six months ended June 30, 2000. The difference was primarily due to unusually high sales levels associated with the withdrawal of one of our competitors products from the market in 2000, as well as increased amortization expense in 2001 due to our recent acquisitions. Net sales grew in fiscal 2000 over calendar 1999 from approximately \$52.2 million to approximately \$68.4 million. We had a net loss in fiscal 2000, before benefit for income taxes and certain nonrecurring items, of approximately \$4.8 million, versus net income up to \$0.2 million for calendar 1999. The difference was primarily due to a more significant write-off of acquired in-process research and development in 2000, as compared to 1999, higher revenues associated with the completion of a multi-year rapid diagnostic test development program in 1999, increased amortization expense in 2000 due to our recent acquisitions, and increases in interest expense and decreases in interest income due to increases in our revolving line of credit to partially finance two acquisitions. We may not continue our revenue growth or achieve profitability. Operating results may continue to fluctuate, in a given quarter or annual period, from prior periods as a result of a number of factors, many of which are outside of our control.

Other factors which are beyond our control and which could affect our results in the future include:

seasonal fluctuations in our sales of Group A Strep and Influenza A/B tests, which are generally highest in fall and winter, thus resulting in generally lower operating results in the second and third calendar quarter and higher operating results in the first and fourth calendar quarters;

changes in the level of competition, such as would occur if one of our larger and better financed competitors introduced a new product to compete with one of our products;

changes in economic conditions in our domestic and international markets, such as economic downturns, reduced consumer demand, inflation and currency fluctuations, particularly as we expand into markets outside Western Europe where economic conditions may differ from those prevailing at given times among developed nations;

delays in shipments of our products to customers or from suppliers which could result from manufacturing difficulties or from unexpected large customer orders which could strain our manufacturing resources; and

changes in sales levels, since a significant portion of our costs are fixed costs with the result that relatively higher sales could likely increase profitability but relatively lower sales would reduce revenue but would not reduce costs by the same proportion, and hence could cause operating losses.

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**Our operating results may also fluctuate as a result of factors which we do control, such as introducing new products or developing new markets. We may have to expend considerable resources in order to pursue these steps, and this could have a negative effect on our profits.**

We must change the mix of products we sell from time to time. For example, while we do not presently have major products that are nearing the end of their life cycle, we may in the future be required to replace aging products. We also attempt to focus on products with relatively higher margins. The development, manufacture and sale of our diagnostic products require a significant investment of resources. We may incur increased operating expenses as a result of our increased investment in sales and marketing activities, manufacturing scale-up and new product development associated with our efforts to:

expand our business line;

take advantage of the new platform we obtained when we acquired Litmus Concepts;

develop products with higher margins, such as our proposed Herpes Simplex Virus antibody test, our microassay to measure bone resorption, and our test for trichomoniasis; and

expand our business geographically.

The funds for these projects came primarily from our business operations, and a working capital line of credit. If our business slows, as we become less profitable, and as a result have less money available to fund research and development, we will have to decide at that time which programs to cut, and by how much. This decision will be based on a number of factors, including the amount of the funding shortfall, how promising a particular project appears to be, and how close the project is to being available commercially. Our operations will be adversely affected if our net sales and gross profits do not correspondingly increase, or if our product development efforts are unsuccessful or delayed. Development of new markets also requires a substantial investment of resources, such as new employees, offices and manufacturing facilities, and if adequate financial, personnel, equipment or real estate resources are not available we may be required to delay or scale back market developments.

**Unexpected significant increases in demand for our products could require us to spend considerable resources to meet the demand, or harm our customer relationships if we are unable to meet demand.**

If we experience unexpected significant increases in the demand for our products, we may be required to expend additional capital resources to meet these demands. These capital resources could involve the cost of new machinery, or even the cost of new manufacturing facilities. This would increase our capital costs, which could affect our earnings. If we are unable to develop necessary manufacturing capabilities, our net sales could be adversely affected. Failure to increase production volumes, if required, in a cost-effective manner, or lower than anticipated yields or

production problems encountered as a result of changes we may make in our manufacturing processes to meet increased demand, could result in shipment delays as well as increased manufacturing costs, which could also have a material adverse effect on our net sales.

Unexpected increases in demand for our products could also require us to obtain additional raw materials in order to manufacture products to meet the demand. The majority of raw materials and purchased components used to manufacture our products are readily available. However, some of these materials are currently obtained from a sole supplier or a limited group of suppliers. For example, our nitro cellulose which is part of the Pregnancy and Group A Strep products, as well as certain plastics, which serve as housings for the majority of our diagnostic test strips are sole sourced. We have long-term supply agreements with these vendors. The reliance on sole or limited suppliers and the failure to maintain long-term agreements with other suppliers involve several risks, including the inability to obtain an adequate supply of raw materials and components and reduced control over pricing, quality and timely delivery. Although we attempt to minimize our supply risks by maintaining an inventory of

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raw materials and continuously evaluating other sources, any interruption in supply could have a material adverse effect on our net sales or cost of sales.

In November 2001, we plan to begin manufacturing our urinalysis products in Marburg, Germany. Currently, we contract with a third party to manufacture these products. Any delays or problems encountered in the integration of this process could result in shipment delays and increased manufacturing costs and could have a material adverse effect on our results of operations.

**The loss of key distributors or an unsuccessful effort to directly distribute our products could lead to reduced sales.**

Although we have distribution agreements with approximately 80 distributors, the market is dominated by a small group of these distributors. Five of our distributors, which are considered to be among the market leaders, accounted for approximately 46% and 40% of our net sales for the six months ended June 30, 2001 and the year ended December 31, 2000, respectively. While we believe our relationship with our distributors is good, the loss of a major distributor may have an adverse effect on our net sales. The loss or termination of our relationship with any of these key distributors could significantly disrupt our business unless suitable alternatives can be timely found. Finding a suitable alternative may pose challenges in our industry's competitive environment, and another suitable distributor may not be found on satisfactory terms. For instance, many distributors already have exclusive arrangements with our competitors, and others do not have the same level of penetration into our target markets as our existing distributors. We could expand our efforts to distribute and market our products directly; however, this would require an investment in additional sales and marketing resources, including hiring additional field sales personnel, which would significantly increase our future selling, general and administrative expenses. In addition, our direct sales, marketing and distribution efforts may not be successful.

**We may not achieve market acceptance of our products among physicians and other health care providers, and this will have a negative effect on future sales growth.**

A large part of our business is based on the sale of rapid point-of-care diagnostic tests that physicians and other health care providers can administer in their own facilities without sending samples to laboratories. Thus, clinical reference laboratories and hospital-based laboratories are significant competitors for our products, and provide many of the diagnostic tests used by physicians and other health care providers. Our market share in fiscal 2000 for some of our key products was 58% in pregnancy tests, 40% in Group Strep A tests and 20% for Influenza A/B tests. Our future sales depend on, among other matters, the capture of sales from these laboratories by achieving market acceptance from physicians and other health care providers. If we do not capture sales at the levels we have budgeted for, our net sales may not grow as much as we hope and the costs we have incurred will be disproportionate to our sales levels. We expect that these laboratories will compete vigorously to maintain their dominance of the testing market. Moreover, even if we can demonstrate that our products are more cost-effective or save time, physicians and other health care providers may resist changing their established source for these tests.

**Intense competition with other manufacturers of point-of-care diagnostic products may reduce our sales.**

In addition to competition from laboratories, our point-of-care diagnostic tests compete with similar products made by our competitors. We have a large number of multinational and regional competitors making investments in competing technologies, including several large pharmaceutical and diversified health care companies. These competitors include Abbott Laboratories, Beckman Coulter Primary Care, and Becton Dickinson. A number of our competitors have a potential competitive advantage because they have substantially greater financial, technical, research and other resources, and

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larger, more established marketing, sales, distribution and service organizations than we have. Moreover, some competitors offer broader product lines and have greater name recognition than we have. If our competitors' products are more effective than ours, or are cheaper, our net sales could be adversely affected. Competition also has the effect of limiting the prices we can charge for our products.

**To remain competitive we must continue to develop or obtain proprietary technology; otherwise, other companies may increase their market share by selling products that compete with our products.**

Our competitive position is heavily dependent on obtaining and protecting our proprietary technology or obtaining licenses from others. Our ability to compete successfully in the diagnostic market depends on continued development and introduction of new proprietary technology and the improvement of existing technology. If we cannot continue to obtain and protect proprietary technology, our net sales and gross profits could be adversely affected. Moreover, our current and future licenses may not be adequate for the operation of our business.

We have a license agreement with Becton Dickinson related to our Pregnancy and Group Strep A products, which accounted for 35% and 36% and 29% and 25% of our net sales, respectively. The license agreement expires in 2004. Our ability to obtain patents and licenses, and their benefits, are uncertain. We have 212 issued patents and approximately 60 applications are pending. Our patents have expiration dates from 2002 to 2017. There are no patents which are expiring in the near term which we consider material to our business. However, our pending patent applications may not result in the issuance of any patents, or if issued, the patents may not have priority over others' applications or may not offer protection against competitors with similar technology. Moreover, any patents issued to us may be challenged, invalidated or circumvented in the future. Further, we have patents issued in Canada, Germany, France, United Kingdom, Italy, Spain, Australia, Belgium, Korea, Norway, Lithuania, the Netherlands, Austria, Switzerland, Sweden and South Africa. Therefore, third parties can make, use, and sell products covered by our patents in any country in which we do not have patent protection. We license the right to use our products to our customers under label licenses that are for research purposes only. These licenses could be contested and, because we cannot monitor all potential unauthorized uses of our products around the world, we might not be aware of an unauthorized use and might not be able to enforce the license restrictions in a cost-effective manner. Also, we may not be able to obtain licenses for technology patented by others or on commercially reasonable terms.

**We may be involved in intellectual property infringement disputes which are costly and could limit our ability to use some technologies in the future.**

There are a large number of patents and patent applications in our product areas, and we believe, based on experience and published reports, that litigation in our industry regarding patent and other intellectual property rights is prevalent. We are not currently involved in any litigation in this area, but our involvement in litigation to determine rights in proprietary technology could adversely affect our net sales because:

in common with any major litigation, it would likely consume a substantial portion of managerial and financial resources;

of the developing state of the law in this area, in the U.S., and around the world, its outcome would be uncertain and a court may find the third-party claims valid and that we have no successful defense to such claims;

an adverse outcome could subject us to significant liability in the form of penalties, special and punitive damages, or future royalty payments affecting our future earnings;

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failure to obtain a necessary license upon an adverse outcome could prevent us from selling our current products or other products we may develop; and

of the developing state of the law, protection of our rights may not be available under the law or may be inadequate.

**The uncertainty and cost of regulatory approval for our products may have a negative effect on our profitability.**

The testing, manufacture and sale of our products are subject to regulation by numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. The FDA regulates all of our products except our veterinary product Heska, which is regulated by the U.S. Department of Agriculture. Our future performance depends on, among other matters, our estimates as to when and at what cost we will receive regulatory approval for new products. However, complying with laws and regulations of these regulatory agencies can be a

lengthy, expensive and uncertain process making the timing and costs of approvals difficult to predict. Our FDA regulated products are categorized as Class I, II and III medical devices, depending on the level of regulation that the FDA believes is necessary to establish safety and efficacy. Depending on the classification of the device, these products need to have either 510(k) or premarket approval prior to distribution. The 510(k) process requires us to submit extensive clinical data, and can take at least three to six months before approval is granted. The premarket approval application must be supported by valid scientific evidence demonstrating the safety and effectiveness of the device, typically including the results of clinical investigations, trials, and laboratory and animal studies. This process can take several years, and is expensive and uncertain. We currently have no pending 510(k) FDA applications or premarket approvals. Our products are also subject to testing under the Clinical Laboratory Improvement Act of 1988, which regulates laboratories and includes quality control, proficiency testing of personnel, personnel standards and physical inspections. We have one application pending under this statute, which was filed in 1999. While we have not to date experienced any unexpected action by any governmental regulatory body, our net sales would be negatively affected by delays in the receipt of or failure to receive approvals or clearances, the loss of previously received approvals or clearances or the placement of limits on the use of the products.

**We are subject to numerous government regulations in addition to FDA regulation, compliance with changes in which could increase our expenses.**

In addition to the FDA and other regulations described in the previous paragraph, numerous laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances impact our business operations. If these laws change, are amended, or are added to, the costs of compliance with these laws could substantially increase our costs. While we believe we currently are in compliance with these laws, compliance with any future modifications of these laws or laws regulating the manufacture and marketing of our products could result in substantial costs and loss of sales or customers. Because of the number and extent of the laws and regulations affecting our industry, and the number of governmental agencies whose actions could affect our operations, it is impossible to reliably predict the full nature and impact of future legislation or regulatory developments relating to our industry. We do not estimate that we will have material capital expenditures for environmental control facilities for the remainder of our current fiscal year or the succeeding fiscal year. To the extent the costs and procedures associated with meeting new requirements are substantial, our business and results of operations could be adversely affected.

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**We use hazardous materials in our business that may result in unexpected and substantial claims against us relating to handling, storage or disposal.**

Our research and development and manufacturing activities involve the controlled use of hazardous materials, including chemicals and biological materials such as dimethyl sulfate, sodium nitrite, acetaldehyde, acrylamide, potassium bromate and radionuclides. The risk of accidental contamination or injury from these materials cannot be completely eliminated. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. These regulations include federal statutes popularly known as CERCLA, RCRA and the Clean Water Act. Compliance with these laws and regulations is expensive. If any governmental authorities were to impose new environmental regulations requiring compliance in addition to that required by existing regulations, these future environmental regulations could impair our research, development or production efforts by imposing substantial costs on our business. In addition, because of the nature of the penalties provided for in some of these environmental regulations, we could be required to pay substantial fines, penalties or damages in the event of noncompliance with environmental laws or the exposure of individuals to hazardous materials. Further, any accident could partially or completely shut down our research and manufacturing facilities and operations.

**Our net sales could be affected by third-party reimbursement policies and potential cost constraints.**

We sell many of our products to physicians and other health care providers. They will not use our products if they do not get reimbursed for the cost by their patients' health care insurers or payors, such as Blue Cross, Blue Shield, Medicare, or other public or private health care programs. Our net sales could be adversely affected by changes in reimbursement policies of these governmental or private health care payors. In the U.S., health care providers such as hospitals and physicians that purchase diagnostic products generally rely on third party payors, principally private health insurance plans, federal Medicare and state Medicaid, to reimburse all or part of the cost of the procedure. We believe that the overall escalating cost of medical products and services has led to and will continue to lead to increased pressures on the health care industry, both foreign and domestic, to reduce the cost of products and services, including our products. Given the efforts to control and reduce health care costs in the U.S. in recent years, currently available levels of reimbursement may not continue to be available in the future for our existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either U.S. or foreign markets, current reimbursement amounts may be decreased in the future and future legislation, regulation or reimbursement policies of third-party payors may reduce the demand for our products or our ability to sell our products on a profitable basis.

**If we are not able to manage our growth strategy, and if we experience difficulties integrating acquired companies or technologies after the acquisition, our earnings may be adversely affected.**

We recently acquired two businesses, Litmus Concepts and a division of Dade Behring Marburg GmbH. Our business strategy contemplates further increased growth in the number of employees, the scope of operating and financial systems and the geographic area of our operations, including further expansion outside the United States, as new products are developed and commercialized. We may experience difficulties integrating our own operations with those of companies or technologies that we have acquired or we may acquire, and as a result we may not realize our anticipated benefits and cost savings within our expected time frame, or at all. Because we do not have a large executive staff, future growth may also divert management's attention from other aspects of our business, and will place a strain on existing management, as well as on our operational, financial and management information systems. Furthermore, we may expand into markets in which we have less experience or incur higher costs. Should we encounter difficulties in managing these tasks, our growth strategy may suffer and our net sales and gross profits could be adversely affected.

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**Our business could be negatively affected by the loss of key personnel or our inability to hire qualified personnel.**

Our future success depends in part on our ability to retain our key technical, sales, marketing and executive personnel and our ability to identify and hire additional qualified personnel. Competition for these personnel is intense, both in the industry in which we operate and also in the geographic area (Northern San Diego County) where our headquarters and many of our operations are located. If we are not able to retain existing key personnel, or identify and hire additional qualified personnel, our business could be negatively impacted. Although we currently experience relatively low rates of turnover for our management and key personnel, the rate of turnover may increase in the future. In addition, we expect to further grow our operations, and our needs for additional management and other key personnel will increase.

**We are exposed to business risks which, if not covered by insurance, could have an adverse effect on our profits.**

We maintain insurance which we believe is appropriate to protect us against the kinds of insurable risks, such as product liability claims or business interruptions, that companies of our size and companies in our industry typically insure against. However, there is a risk that claims may be made against us for types of damages, or for amounts of damages, that are not covered by our insurance. For example, there is a risk of product liability claims arising from our testing, manufacturing and marketing of medical diagnostic devices, both those currently being marketed as well as those under development. We currently have a product liability policy providing coverage up to \$10 million, and our claims to date have not been material. However, it is possible that potential product liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy. Also, if we are held liable, our existing insurance may not be renewed at the same cost and level of coverage as presently in effect, or may not be renewed at all. If we are held liable for a claim against which we are not indemnified or for damages exceeding the limits of our insurance coverage, whether arising out of product liability matters or from some other matter, that claim could have a material negative effect on our results of operations.

**We face risks relating to our international sales and foreign operations, including the risk of currency fluctuations, which could increase our costs or stifle our growth opportunities.**

Our products are sold internationally, primarily at this time to customers in Western Europe, including Germany and Italy, and also Poland. Sales to foreign customers accounted for 23% and 25% of our net sales for the six months ended June 30, 2001 and the year ended December 31, 2000, respectively, and are expected to continue to account for a significant percentage of our net sales. For example, our business strategy calls for the launch of a worldwide basis of our proposed herpes simplex virus antibody rapid diagnostic test, and marketing our Influenza A/B test on a worldwide basis. Moreover, while we do not currently manufacture any product overseas, we do have our urinalysis products manufactured for us by a third party in Germany and in November 2001, we will commence manufacture of all urinalysis products in Germany ourselves. International sales and manufacturing operations are subject to inherent risks which could increase our costs and stifle our growth opportunities. These risks include:

exposure to currency exchange fluctuations, such as a 7% drop in the value of the German and Italian currencies against the U.S. dollar during fiscal 2000;

longer payment cycles and greater difficulty in accounts receivable collection;

compliance with multiple foreign laws, tariffs or other barriers as we continue to expand into new countries and geographic regions;

difficulties in obtaining export licenses;

reduced protection for, and enforcement of, intellectual property rights, particularly as we expand our business beyond Europe;

political and economic instability in some of the regions that we may expand into in the future; and

potentially adverse tax consequences.

Even that portion of our international sales which is negotiated for and paid in U.S. dollars is subject to currency risks, since changes in the values of foreign currencies relative to the value of the U.S. dollar can render our products comparatively more expensive. These exchange rate fluctuations could negatively impact international sales of our products and our anticipated foreign operations, as could changes in the general economic conditions in those markets. In fiscal 2000, for example, the value of the German and Italian currencies dropped 7% against the U.S. dollar. To date, we have not reflected that change in currency value in our selling prices. In order to maintain a competitive price for our products in Europe, however, we may have to provide discounts or otherwise effectively reduce our prices, resulting in a lower margin on products sold in Europe. Continued change in the values of European currencies or changes in the values of other foreign currencies could have a negative impact on our business, financial condition and results of operations. Although we do not currently hedge against exchange rate fluctuations, any measures we take to hedge against exchange rate fluctuations may not adequately protect us from their potential harm.

**We rely on a continuous power supply to conduct our operations, and California's current energy crisis could disrupt our operations and increase our expenses.**

California is in the midst of an energy crisis that could disrupt our operations and significantly increase our expenses. In the event of an acute power shortage, that is, when power reserves for the State of California fall below 1.5%, California has on some occasions implemented, and may in the future continue to implement, rolling blackouts throughout California. We currently have a backup generator with limited capacity. We have no alternate source of power in the event of a blackout, and our current insurance does not provide coverage for any damages we or our customers may suffer as a result of any interruption in our power supply. If blackouts interrupt our power supply, we would be temporarily unable to continue operations at our facilities. Any such interruption in our ability to continue operations at our facilities could damage our reputation, harm our ability to retain existing customers and to obtain new customers, and could result in lost revenue, any of which could substantially harm our business and results of operations. Furthermore, our utility expenses have increased substantially and could continue to be negatively impacted by the California energy crisis.

**Future sales by existing stockholders could depress the market price of our common stock and make it more difficult for us to sell stock in the future.**

Sales of our common stock in the public market, or the perception that such sales could occur, could negatively impact the market price of our securities and impair our ability to complete equity financings. In addition to the shares to be sold in this offering, we have outstanding the following shares of common stock:

Approximately 25.0 million shares of common stock that have been issued in registered offerings and are freely tradable in the public markets.

Approximately 3.2 million shares of common stock currently eligible for resale in the public market pursuant to Rule 144 under the Securities Act of 1933, as amended.

In addition, approximately 5.3 million shares of common stock are issuable upon exercise of stock options outstanding as of June 30, 2001 under our various stock option plans at a weighted average exercise price of \$4.18 per share.



We have in effect registration statements under the Securities Act registering approximately 6.5 million shares of common stock reserved under our employee stock option and purchase plans.

We have in effect a registration statement under the Securities Act registering approximately 1.0 million shares of common stock issuable upon exercise of warrants, which warrants are themselves freely tradeable.

We are unable to estimate the number of shares of common stock that may actually be resold in the public market since this will depend upon the market price for the common stock, the individual circumstances of the sellers and other factors. We also have a number of individual institutional stockholders that own significant blocks of our common stock. If these stockholders sell large portions of their holdings in a relatively short time, for liquidity or other reasons, the prevailing market price of our common stock could be negatively affected.

### **ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission. This prospectus provides you with a general description of the securities being offered. Please carefully read both this prospectus and any applicable prospectus supplement, together with additional information described under the heading "Where You Can Find More Information" on page 18 of this prospectus.

### **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

In this prospectus we have used some "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995, which means that we have used statements containing projections, or statements of the expectations, plans or objectives of our management, or statements of future economic performance. Some of these statements are based on the beliefs of our management, and on management assumptions based on information that is currently available to us. We usually use the words "estimate," "project," "believe," "anticipate," "intend," "expect" and similar expressions to identify these forward-looking statements. These statements reflect our current views with respect to future events. They are subject to risks and uncertainties that could cause actual results to be very different from the predictions and assumptions contemplated in the forward-looking statements. Do not place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus.

### **USE OF PROCEEDS**

We will not receive any proceeds from the sale of the shares of common stock by the selling stockholders.

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### **SELLING STOCKHOLDERS**

The shares of our common stock covered by this prospectus were issued to former shareholders and certain optionholders of Litmus, in a transaction in which Litmus became a wholly owned subsidiary of ours. In a series of private transactions, we issued approximately 3,250,000 shares of our common stock to former shareholders and certain optionholders of Litmus, pursuant to the terms of the merger agreement between us and Litmus. Almost all of these shares were prohibited from being sold until June 6, 2001, pursuant to lock-up agreements executed by us and certain of the selling stockholders. Of these shares, 2,486,514 shares are the subject of this prospectus. The remaining 763,486 shares issued in connection with the merger are subject to an escrow agreement as security against breaches of certain representations and warranties made by Litmus. Of these escrowed shares, 32,580 have been released to us from escrow, due to a cash payment made by us to a third party on behalf of Litmus for financial advisory fees, and 730,906 remain in escrow. Under a registration rights agreement dated December 8, 2000, we agreed to register the shares that were not placed in escrow and maintain the effectiveness of the registration statement until the earlier of one year from effectiveness or the date on which all the shares covered by this prospectus have been sold. For more information on distribution of the shares, see "Plan of Distribution" on page 16 of this prospectus. The selling stockholders may from time to time offer and sell pursuant to this prospectus any or all of the 2,486,514 shares of our common stock. The table below describes, as of August 31, 2001, the number of shares of our common stock covered by this prospectus that each selling stockholder beneficially owns. The term "selling stockholders" includes the holders listed below and their transferees, pledgees, donees or other successors. We have prepared this table based upon information furnished to

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us by or on behalf of the selling stockholders.

The selling stockholders confirmed at the time they acquired the shares listed below that they acquired the shares for investment purposes only and not with a view toward their resale, and acknowledged the existence of restrictions on resale that apply to these shares. This offering relates only to the sale of shares held or to be held by the selling stockholders named in the following table. Since the date on which they provided us with the information below, the selling stockholders may have sold, transferred or otherwise disposed of some or all of their shares of our common stock in transactions exempt from the Securities Act's registration requirements.

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Selling Stockholders	Shares Beneficially Owned Prior to Offering		Number of Shares Being Registered For Sale	Shares Beneficially Owned if All Shares Being Registered Are Sold(2)	
	Number of Shares	Percent(1)		Number of Shares	Percent(1)
Mary Lynne Ament	3,684	*	2,847	837	*
Terrence Andreasen	5,577	*	4,310	1,267	*
Jason Barzilay	3,928	*	3,036	892	*
Beacon Fiduciary Advisors, Inc.	73,673	*	56,937	16,736	*
Alison P. Bisno	3,684	*	2,847	837	*
Alexander Blass	1,964	*	1,518	446	*
Constance Blass O'Neill Trust #3	7,367	*	5,694	1,673	*
Constance Blass O'Neill, Trustee for Amanda Beverly O'Neill	2,947	*	2,278	669	*
Constance Blass O'Neill, Trustee for Isabel Leaman O'Neill	2,947	*	2,278	669	*
Constance Blass O'Neill, Trustee for John Blass O'Neill	2,947	*	2,278	669	*
Constance Blass O'Neill, Trustee for Kristen Patricia O'Neill	2,947	*	2,278	669	*
Gus Blass II	80,538	*	62,242	18,296	*
Gus Blass III	22,190	*	17,149	5,041	*
Gus Blass III Keough Account	36,836	*	28,468	8,368	*
Patricia B. Blass	7,367	*	5,694	1,673	*
Rebecca Blass	982	*	759	223	*
Charlotte & Curt Bradbury	3,684	*	2,847	837	*
Marian B. Buccafurni	319,617	1.13%	247,009	72,608	*
Marian Buccafurni & Paul Lawrence	3,684	*	2,847	837	*
Harriet Calhoun Stephens Trust	2,211	*	1,709	502	*
Capital Properties, Ltd.	85,088	*	65,759	19,329	*
C.E. Unterberg, Towbin LLC	4,910	*	3,795	1,115	*
John Chan & Lily W. Chan	3,684	*	2,847	837	*
William H. Chan, MD	14,735	*	11,388	3,347	*
William H. Chan, MD & Janet Wong, DDS	8,840	*	6,832	2,008	*
Aulena Chaudhuri	4,169	*	3,222	947	*
Sally Chew	7,367	*	5,694	1,673	*
Betsy Cohen	6,098	*	4,713	1,385	*
CooperSurgical Acquisition Corp.	1,473,453	5.19%	1,138,725	334,728	1.19%
Coral Partners	3,684	*	2,847	837	*
Coral Two Corporation	11,051	*	8,541	2,510	*
Steve Costella	540	*	417	123	*
Eric Daniel	3,684	*	2,847	837	*
Peter Davis	15,750	*	12,172	3,578	*
Lou De Amicis	4,065	*	3,141	924	*
Alan Dror, MD	10,020	*	7,743	2,277	*
William W. R. Elder	3,684	*	2,847	837	*
Webb J. Engman & Marie J. Engman	1,179	*	911	268	*

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	Shares Beneficially Owned Prior to Offering		Shares Beneficially Owned if All Shares Being Registered Are Sold(2)		
Douglas Engman Fires & Patricia J. Fires	1,179	*	911	268	*
Leroy Fong & Julie Fong	3,684	*	2,847	837	*
Donald Freedlander	3,684	*	2,847	837	*

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Regina Gindin	5,893	*	4,555	1,338	*
Richard Giss	1,473	*	1,138	335	*
Robert Giss	1,473	*	1,138	335	*
Vernon Giss	1,473	*	1,138	335	*
Warren Giss	1,473	*	1,138	335	*
Henry & Sheila Gladstone	3,684	*	2,847	837	*
Carol Green	5,893	*	4,554	1,339	*
William F. Green	148	*	114	34	*
Carol Hall	1,220	*	943	277	*
RMH, III Age 21 Trust	982	*	759	223	*
WSW Hamilton Age 21 Trust	982	*	759	223	*
Robert M. Hamilton, Jr.	11,051	*	8,541	2,510	*
Michealle Havenhill	414	*	320	94	*
Henry Heines	7,749	*	5,988	1,761	*
Mark Herrman	7,367	*	5,694	1,673	*
Gail Highberg	1,584	*	1,224	360	*
Thomas Ingram	1,964	*	1,518	446	*
Joan Irwin	737	*	569	168	*
J. Chasnoff Joint Venture #6	5,893	*	4,554	1,339	*
Roland Jang	18,928	*	14,628	4,300	*
Jeffrey Jones	148	*	114	34	*
Stanley Keller	7,367	*	5,694	1,673	*
Bill Kirsch	540	*	417	123	*
The Lampert Irrevocable Trust Julie Bell, Trustee	1,473	*	1,138	335	*
Roland Lampert	68,470	*	52,915	15,555	*
Ellen B. Laner Trust	7,367	*	5,694	1,673	*
Leah Lawrence	4,658	*	3,600	1,058	*
Paul J. Lawrence	391,790	1.38%	302,786	89,004	*
Diem Le	28	*	22	6	*
Sheng Fen Li	330	*	255	75	*
Peter Ly	5,225	*	4,038	1,187	*
Douglas H. Martin	2,947	*	2,278	669	*
Dennis McGee	1,989	*	1,537	452	*
Robert McGee	148	*	114	34	*
Glen McLaughlin	19,054	*	14,726	4,328	*
Glen Wallace McLaughlin	3,684	*	2,847	837	*
MH Fund, Inc.	35,363	*	27,329	8,034	*
Allen Misher	29,761	*	23,000	6,761	*
Karen Morrical	1,473	*	1,138	335	*
Mark Morris	2,434	*	1,881	553	*
William Muttera	1,220	*	943	277	*
Teresa M. Nippes	4,065	*	3,141	924	*
Debbie Nishijima	428	*	331	97	*
Norman Family Investments LP	4,715	*	3,644	1,071	*
Rebecca O'Brien	4,269	*	3,299	970	*
Robert O'Callaghan	589	*	455	134	*

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Constance O'Neill	3,928	*	3,036	892	*
David M. O'Malley	4,065	*	3,141	924	*
John O'Malley	73,808	*	57,040	16,768	*

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John A. O'Malley, Jr.	4,065	*	3,141	924	*
Robert D. O'Malley	4,065	*	3,141	924	*
Joseph Ogrinc	295	*	228	67	*
Patrick B. Parmelee	148	*	114	34	*
Perry O. Parmelee & Joan W. Parmelee, Trustees of the Parmelee Trust U/D/T Dtd 5/24/93	2,211	*	1,709	502	*
Robert Pena	21	*	16	5	*
Lawrence S. Phillips	36,836	*	28,468	8,368	*
Roxane Phillips	1,473	*	1,138	335	*
Scott Read	1,291	*	998	293	*
James Reinsch	237	*	183	54	*
Cynthia Robbins-Roth	1,220	*	943	277	*
William Rohn	295	*	228	67	*
Louis Rosen & Vivan B. Rosen	7,367	*	5,694	1,673	*
Hank Sakai	5,893	*	4,554	1,339	*
Julie A. Saunders	1,473	*	1,138	335	*
Heresh Shah	6,098	*	4,713	1,385	*
Donny Shapiro	186	*	144	42	*
David Shockey	4,065	*	3,141	924	*
Ben Simon	3,928	*	3,036	892	*
Arthur Small, Jr.	5,009	*	3,871	1,138	*
J. G. Stuckey	1,473	*	1,138	335	*
David Sutton	3,169	*	2,449	720	*
Bess Stephens Family Trust	35,363	*	27,329	8,034	*
Jackson T. Stephens Trust One	20,628	*	15,942	4,686	*
Warren A. Stephens & Harriet C. Stephens Childrens Trust	3,684	*	2,847	837	*
Warren A. Stephens, Trustee of the Warren A. Stephens Trust	8,840		6,832	2,008	*
Mya Myat Tun	212	*	164	48	*
Barry Waxman	3,684	*	2,847	837	*
Gordon A. Wong, MD & Merrily F. Wong	25,785	*	19,927	5,858	*
Gordon Wong, MD	3,684	*	2,847	837	*
Elmar Zanflorin	3,684	*	2,847	837	*

- \*  
Less than 1%.
- (1)  
Computed based on 28,363,305 shares of common stock outstanding as of August 31, 2001.
- (2)  
Assumes all of the shares of common stock that may be offered hereunder are sold.

**RELATIONSHIPS WITH SELLING STOCKHOLDERS**

As part of our acquisition of Litmus, we entered into certain agreements with key employees and related parties of Litmus who are among the selling stockholders listed above. Among these are the following material agreements:

A consulting, severance and general release agreement with Marian Buccafurni, formerly an officer of Litmus, whereby Ms. Buccafurni will provide consulting services for a two year period at \$75,000 per year. Ms. Buccafurni also received \$66,000 under the severance agreement.

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An employment agreement with Paul Lawrence, under which Mr. Lawrence is to be employed as Vice President and Chief Technology Officer for two years, with compensation consisting of an annual salary of \$190,000, a signing bonus of \$50,000, and an option to purchase 200,000 shares of our common stock.

We paid a \$1.0 million license fee to an affiliate of CooperSurgical Acquisition Corp., for the co-exclusive right to sell Litmus products in the U.S.

In connection with the acquisition of Litmus, we leased a facility from an affiliate of Capital Properties, Ltd. The lease is for nine years with total future rental payments of approximately \$8.6 million.

Other than these agreements, there have been no material relationships or agreements between us and the selling stockholders within the last three years.

### PLAN OF DISTRIBUTION

The selling stockholders can use this prospectus to sell the shares at any time while the prospectus is in effect, unless the shares are subject to other resale restrictions or we have notified the selling stockholders that the prospectus is not available at that particular time. The selling stockholders in their discretion will determine if, when and how they will sell the shares they own. We do not know when or whether the selling stockholders will offer their shares for sale to the public. Any sales by the selling stockholders may occur in one or more of the following types of transactions (including block transactions):

transactions on the Nasdaq National Market or any other organized market or quotation system where the shares may be traded,

privately negotiated transactions between a selling stockholder and a purchaser, or

transactions effected with or through a broker-dealer acting as either agent or principal.

These transactions may involve the transfer of the shares upon exercise or settlement of put or call options, the covering of short sales or loaning of the shares to others to effect short sales or a combination of such methods. If a broker-dealer is used in the sale of shares, that person may solicit potential purchasers. The shares may also be transferred as a gift or as a result of a pledge, or may be sold to a broker-dealer acting as principal. These persons may then sell the shares to another person, either directly or through another broker-dealer, subject to compliance with the requirements of the Securities Act.

The price at which sales of the shares occur may be based on market prices or may be negotiated between the parties to such sales, and the consideration may be cash or another form negotiated between the parties. Transactions in the shares may be effected by brokers, dealers or agents engaged by the selling stockholders. Broker-dealers acting as agents or principals may be paid compensation in the form of discounts, concessions or commissions from the selling stockholder and/or from the purchasers of the shares, or both. Discounts, concessions, commissions and similar selling expenses, if any, that can be attributed to the sale of shares will be paid by the selling stockholder and/or the

purchasers. Brokers, dealers or other agents may be deemed to be "underwriters" within the meaning of the Securities Act. Any profits on the resale of shares by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on it under the Securities Act.

The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their shares, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of shares by any selling stockholder. If we are notified by any selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares, if required, we will file a supplement to this prospectus.

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If the selling stockholders use this prospectus for any sale of the shares, they will be subject to the prospectus delivery requirements of the Securities Act. For transactions effected on or through the Nasdaq National Market, those requirements may be satisfied by our delivery of copies of this prospectus to the Nasdaq National Market in compliance with Securities Act Rule 153. Instead of using this prospectus for any sale of the shares, a selling stockholder may resell shares in compliance with the criteria and requirements of Securities Act Rule 144.

The anti-manipulation rules of Regulation M under the Securities Exchange Act of 1934 may apply to sales of our common stock and activities of the selling stockholder.

We have agreed to pay certain of the costs, expenses and fees of preparing, filing and maintaining this prospectus and the registration statement of which this prospectus is a part, but we will not receive any proceeds from sale of the shares subject to this prospectus. We have also agreed, under a registration rights agreement, to keep the registration statement, of which this prospectus and any subsequent prospectuses constitute a part, effective until the earlier of one year after effectiveness or until all the shares covered by this registration statement have been sold. Pursuant to the registration rights agreement, we will extend the effective period of this prospectus if, during the effective period, we suspend the effectiveness of the prospectus for reasons specified in the registration rights agreement with the selling stockholders. Also pursuant to the registration rights agreement, we have agreed to indemnify the selling stockholders, and the selling stockholders have agreed to indemnify us, and each has agreed to indemnify other persons named or described in the registration rights agreement, against various liabilities, including liabilities under the federal Securities Exchange Act and state securities laws.

We intend to distribute copies of this prospectus to the record holders of our shares covered by this prospectus promptly following the effective date of the registration statement of which this prospectus forms a part. We also intend to distribute copies of any supplemented or revised prospectuses to the selling stockholders.

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### LEGAL MATTERS

The validity of the shares of common stock covered by this prospectus will be passed upon by Gibson, Dunn & Crutcher LLP, 4 Park Plaza, Jamboree Center, Irvine, California 92614.

### EXPERTS

The audited consolidated financial statements and schedule of Quidel Corporation and the audited financial statements of Litmus Concepts, Inc. incorporated by reference in this prospectus and elsewhere in the registration statement, to the extent and for the periods indicated in their reports, have been audited by Arthur Andersen LLP, independent public accountants and are included herein in reliance upon the authority of said firm as experts in giving said reports.

The consolidated statements of operations, stockholders' equity and cash flows incorporated by reference in this prospectus and elsewhere in the registration statement, to the extent and for the periods indicated their report, have been audited by Ernst and Young LLP, independent auditors, and are included herein in reliance upon the authority of said firm as experts in giving said report.

### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. You may read or copy any document that we file with the Securities and Exchange Commission at the Commission's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information about the Public Reference Room by calling the Securities and Exchange Commission for more information at 1-800-SEC-0330. Our filings are also available at the Securities and Exchange Commission's web site at <http://www.sec.gov>.

We filed a registration statement on Form S-3 with the Securities and Exchange Commission that covers the sale of the shares offered in this prospectus. This prospectus is part of that registration statement, but does not include all of the information included in the registration statement. You should refer to the registration statement for additional information about us and the shares offered in this prospectus. Statements that we have made in this prospectus relating to any document filed as an exhibit to the registration statement or any document incorporated by reference into the registration statement may not be complete. You should review the referenced document itself for a complete understanding of its terms.

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The Securities and Exchange Commission allows us to "incorporate by reference" the information that we have filed with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Later information that we file with the Securities and Exchange Commission automatically will update and supersede the information contained in this prospectus. We are incorporating by reference the documents listed below and any future filings that we will make with the Securities and Exchange Commission under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934:

1. Our Quarterly Report on Form 10-Q/A for the quarter ended June 30, 2001, filed on September 24, 2001.
2. Our Quarterly Report on Form 10-Q/A for the quarter ended March 31, 2001, filed on September 24, 2001.
3. Our Annual Report on Form 10-K/A for the year ended December 31, 2000, filed on September 24, 2001.
4. Our Proxy Statement for the Annual Meeting of Shareholders on May 23, 2001, filed on April 17, 2001.

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5. Our Form 8-K/A filed on February 21, 2001.
6. The description of our Preferred Stock Purchase Rights contained in our Registration Statement on Form 8-A filed on January 13, 1997, including any amendment or report filed for the purpose of updating such description.
7. The description of our common stock contained in the Registration Statement on Form 8-A dated February 28, 1983, including any amendment or report filed for the purpose of updating such description.

We will provide to you, without charge, a copy of the documents that we have incorporated by reference in this prospectus (other than exhibits to such documents unless those exhibits are specifically incorporated by reference into this prospectus). Written or oral requests for documents should be directed to Investor Relations, at 10165 McKellar Court, San Diego, CA 92121 (Telephone: (858) 552-1100).

You should only rely on the information included in or incorporated by reference into this prospectus. We have not authorized anyone to provide you with additional or different information. You should not assume that the information in this prospectus or any supplement is accurate as of any date other than the date of that document.

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