APPLIED BIOTECH INC / Form S-4 November 26, 2010

As filed with the Securities and Exchange Commission on November 26, 2010 Registration No. 333-

## SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### Form S-4

# REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

## ALERE INC. See Table of Additional Registrants Below

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

2835

(Primary Standard Industrial Classification Code)

04-3565120

(I.R.S. Employer Identification Number)

51 Sawyer Road, Suite 200 Waltham, Massachusetts 02453 (781) 647-3900

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Ron Zwanziger Chairman, Chief Executive Officer and President 51 Sawyer Road, Suite 200 Waltham, Massachusetts 02453 (781) 647-3900

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

#### With copies to:

John D. Patterson, Jr., Esq. Foley Hoag LLP 155 Seaport Boulevard Boston, Massachusetts 02210 (617) 832-1000 Jay McNamara, Esq.
Senior Counsel, Corporate & Finance
Alere Inc.
51 Sawyer Road, Suite 200
Waltham, Massachusetts 02453
(781) 647-3900

**Approximate date of commencement of proposed sale to the public:** As soon as possible after the effective date of this registration statement.

If the securities being registered on this form are being offered in connection with the formation of a holding company and there is compliance with General Instruction G, check the following box. o

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o\_\_\_\_\_

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o\_\_\_\_\_

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer b Accelerated filer o Non-accelerated filer o Smaller reporting company o (Do not check if a smaller reporting company)

If applicable, place an X in the box to designate the appropriate rule provision relied upon in conducting this transaction:

Exchange Act Rule 13e-4(i) (Cross-Border Issuer Tender Offer) o

Exchange Act Rule 14d-1(d) (Cross-Border Third-Party Tender Offer) o

#### CALCULATION OF REGISTRATION FEE

**Proposed Maximum** Proposed Maximum Amount of

Edgar Filing: APPLIED BIOTECH INC / - Form S-4

Title of Each Class of Securities to be Registered	Amount to be Registered	Offering Price per Unit(1)	Aggregate Offering Price(1)	Registration Fee
8.625% Senior Subordinated				
Notes due 2018	\$400,000,000	100%	\$400,000,000	\$28,520
Guarantees of 8.625% Senior				
Subordinated Notes due 2018	(2)	(2)	(2)	(2)

- (1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(f) under the Securities Act of 1933, as amended.
- (2) Pursuant to Rule 457(n), no separate fee is payable for the guarantees.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

#### TABLE OF ADDITIONAL REGISTRANTS

The direct and indirect wholly owned domestic subsidiaries of Alere Inc. listed in the table below are expected to guarantee the debt securities issued pursuant to this registration statement. The address, including zip code, and telephone number, including area code, of each of the co-registrants is 51 Sawyer Road, Suite 200, Waltham, Massachusetts, 02453, (781) 647-3900.

Exact Name of Additional Registrant as Specified in its Charter	State or Other Jurisdiction of Incorporation or Organization	I.R.S. Employer Identification Number
Alere Health Improvement Company	Delaware	23-2776413
Alere Health, LLC	Delaware	26-2564744
Alere Health Systems, Inc.	Delaware	22-3493126
Alere Healthcare of Illinois, Inc.	Georgia	58-2068880
Alere Home Monitoring, Inc.	Delaware	20-0391730
Alere International Holding Corp.	Delaware	20-0963463
Alere Medical, Inc.	California	94-3238845
Alere NewCo, Inc.	Delaware	27-2104833
Alere NewCo II, Inc.	Delaware	27-2104868
Alere North America, Inc.	Delaware	26-1444559
Alere San Diego, Inc.	Delaware	33-0288606
Alere Scarborough, Inc.	Delaware	20-2507302
Alere Toxicology Services, Inc.	Louisiana	72-0846066
Alere US Holdings, LLC	Delaware	26-0349667
Alere Wellology, Inc.	Delaware	54-1776557
Alere Women s and Children s Health, LLC	Delaware	58-2205984
Ameditech Inc.	California	33-0859551
Applied Biotech, Inc.	California	33-0447325
Binax, Inc.	Delaware	36-4668096
Biosite Incorporated	Delaware	27-2104785
Cholestech Corporation	Delaware	94-3065493
First Check Diagnostics Corp.	Delaware	20-8329751
First Check Ecom, Inc.	Massachusetts	33-1026518
Free & Clear, Inc.	Delaware	20-0231080
GeneCare Medical Genetics Center, Inc.	North Carolina	56-1348485
Hemosense, Inc.	Delaware	77-0452938
Innovacon, Inc.	Delaware	20-1100264
Instant Technologies, Inc.	Virginia	54-1837621
Inverness Medical Biostar Inc.	Delaware	91-1929582
Inverness Medical, LLC	Delaware	26-0392649
IVC Industries, Inc.	Delaware	22-1567481
Laboratory Specialists of America, Inc.	Oklahoma	73-1451065
Matria of New York, Inc.	New York	58-1873062
Matritech, Inc.	Delaware	26-1436477
Ostex International, Inc.	Washington	91-1450247

Florida 59-3437644	Quality Assured Services, Inc.
ry, Inc. California 68-0332937	Redwood Toxicology Laboratory, Inc.
Delaware 84-1581993	RMD Networks, Inc.
Delaware 20-4371685	RTL Holdings, Inc.
Inc. Virginia 54-1624514	Scientific Testing Laboratories, Inc.
Delaware 04-3383533	Selfcare Technology, Inc.
Delaware 37-1485678	Wampole Laboratories, LLC
North Carolina 56-1398496	ZyCare, Inc.
Delaware 84-1581993 Delaware 20-4371685 Inc. Virginia 54-1624514 Delaware 04-3383533 Delaware 37-1485678	RMD Networks, Inc. RTL Holdings, Inc. Scientific Testing Laboratories, Inc. Selfcare Technology, Inc. Wampole Laboratories, LLC

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and we are not soliciting an offer to buy these securities, in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated November 26, 2010

**Prospectus** 

#### **ALERE INC.**

OFFER TO EXCHANGE
ALL \$400,000,000 AGGREGATE PRINCIPAL AMOUNT OF
UNREGISTERED 8.625% SENIOR SUBORDINATED NOTES DUE 2018
ISSUED ON SEPTEMBER 21, 2010
FOR
UP TO \$400,000,000 AGGREGATE PRINCIPAL AMOUNT OF

UP TO \$400,000,000 AGGREGATE PRINCIPAL AMOUNT OF 8.625% SENIOR SUBORDINATED NOTES DUE 2018
THAT HAVE BEEN REGISTERED
UNDER THE SECURITIES ACT OF 1933

This exchange offer and withdrawal rights will expire at 5:00 p.m., New York City time, on , 2011, unless extended.

We are offering to exchange any and all of our outstanding unregistered 8.625% Senior Subordinated Notes due 2018 that we issued on September 21, 2010, referred to in this prospectus as the old notes, for up to \$400.0 million aggregate principal amount of our new 8.625% Senior Subordinated Notes due 2018 that have been registered under the Securities Act of 1933, which we refer to in this prospectus as the new notes and, collectively with the old notes, the 2010 senior subordinated notes. We issued the old notes in a transaction not requiring registration under the Securities Act. We are offering you new notes, with terms substantially identical to those of the old notes, in exchange for old notes in order to satisfy our obligations under a registration rights agreement into which we entered in connection with the offering and sale of the old notes.

#### **Certain Material Terms of the Exchange Offer**

The terms of the new notes are identical in all material respects to the terms of the old notes, except that the terms with respect to transfer restrictions, registration rights and payments of additional interest that relate to the old notes will be inapplicable to the new notes, and the new notes will bear different CUSIP and ISIN numbers than the old notes.

The new notes will be fully and unconditionally guaranteed, jointly and severally, on a senior subordinated basis, subject to certain exceptions, by all of our domestic subsidiaries that guarantee certain of our other indebtedness.

The exchange offer expires at 5:00 p.m., New York City time, on , 2011, which we refer to as the expiration time and the expiration date, respectively, unless extended by us.

Subject to the terms of this exchange offer, we will exchange all of the old notes that are validly tendered and not withdrawn prior to the expiration of the exchange offer.

You may withdraw your tender of old notes at any time before the expiration of this exchange offer.

If you do not properly tender your old notes, you will continue to hold unregistered notes that you will not be able to transfer freely.

The exchange of old notes for new notes generally will not be a taxable event for U.S. federal income tax purposes.

We do not intend to list the new notes on any national securities exchange or seek approval for quotation through any automated trading system.

We will not receive any proceeds from this exchange offer.

All broker-dealers must comply with the registration and prospectus delivery requirements of the Securities Act.

See the section entitled Risk Factors that begins on page 11 for a discussion of the risks that you should carefully consider before tendering your old notes for exchange.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2010

Each broker-dealer that receives new notes for its own account in connection with the exchange offer must acknowledge that it will deliver a prospectus in connection with any resale of such new notes. This prospectus, as it may be amended or supplemented from time to time, may be used by a broker-dealer in connection with resales of new notes received in exchange for old notes acquired by such broker-dealer as a result of market-making activities or other trading activities. We have agreed that, if requested by such a broker-dealer, for a period of 45 days, subject to extension under certain circumstances, after the date of effectiveness of the registration statement of which this prospectus forms a part (or such earlier date on which such broker-dealers no longer hold any old notes), we will make this prospectus, as amended and supplemented, available to any broker-dealer for use in connection with any such resale. See Plan of Distribution. The letter of transmittal delivered with this prospectus states that a broker-dealer, by acknowledging that it will deliver and by delivering a prospectus, will not be deemed to admit that it is an underwriter within the meaning of the Securities Act of 1933, as amended, or the Securities Act.

We have not authorized any broker, dealer or other person to give any information other than that contained or incorporated by reference in this prospectus. You must not rely upon any information not contained or incorporated by reference in this prospectus as if we had authorized it. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the registered securities to which it relates, nor does this prospectus constitute an offer to sell or a solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

#### TABLE OF CONTENTS

About This Prospectus	ii
Where You Can Find More Information	ii
<u>Summary</u>	1
Risk Factors	11
Special Note Regarding Forward-Looking Statements	32
Selected Consolidated Financial Information and Other Data	34
The Exchange Offer	37
Description of New Notes	47
Description of Old Notes	100
Description of Other Indebtedness	100
Material United States Federal Income Tax Consequences	106
Plan of Distribution	109
Legal Matters	110
Experts	110
Incorporation of Documents by Reference	111
<u>EX-5.1</u>	
<u>EX-5.2</u>	
EX-5.3	
EX-5.4 EX-5.5	
EX-5.6	
<u>EX-5.7</u>	
<u>EX-5.8</u>	
EX-5.9	
EX-12.1 EX-12.2	
EX-23.1	
<u>EX-23.2</u>	

EX-23.3 EX-23.4 EX-23.5 EX-23.6	
EX-25.1 EX-99.1 EX-99.2 EX-99.3 EX-99.4	
	i

#### **ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC. We may add, update or change any information contained in this prospectus through a prospectus supplement or another document incorporated by reference into this prospectus. You should read this prospectus and any prospectus supplement, as well as any post-effective amendments to the registration statement of which this prospectus is a part, together with the additional information described under Incorporation of Documents by Reference and Where You Can Find More Information, before you make any investment decision.

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. We are offering to exchange old notes for new notes only in jurisdictions where such offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any actual exchange of old notes for new notes.

Unless otherwise stated or unless the context otherwise requires, all references to we, us, our, our company or the Company in this prospectus refer collectively to Alere Inc., a Delaware corporation, and its subsidiaries, and their respective predecessor entities for the applicable periods, considered as a single enterprise.

#### WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-4 under the Securities Act with respect to the new notes offered hereby. This prospectus, which is a part of the registration statement, does not contain all of the information contained in the registration statement, as amended, or the exhibits and schedules filed with the registration statement. For further information with respect to us and the new notes offered hereby, please see the registration statement, as amended, and the exhibits and schedules filed with the registration statement. Each statement contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. A copy of the registration statement, as amended, and the exhibits and schedules filed with the registration statement may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street, NE, Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from such offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains an internet website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the website is www.sec.gov.

We are subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and we file annual, quarterly and periodic reports, proxy statements and other information with the SEC. Such reports, proxy statements and other information are available for inspection and copying at the public reference room and website of the SEC referred to above.

This prospectus incorporates important business and financial information about the company that is not included in or delivered with this document. You may request a copy of this information and the filings we mention above, at no cost, by writing or calling us at Alere Inc., 51 Sawyer Road, Suite 200, Waltham, Massachusetts, 02453, telephone (781) 647-3900, Attention: Secretary.

To obtain timely delivery of any copies of filings requested, please write or call us no later than days prior to the expiration of the exchange offer.

ii

#### **SUMMARY**

This summary highlights the information appearing elsewhere or incorporated by reference in this prospectus. Because it is only a summary, it does not contain all the information that may be important to you or that you should consider before exchanging your old notes for new notes. You should carefully read this entire prospectus, including the Risk Factors section, and the documents incorporated by reference in the prospectus and should consult with your own legal and tax advisors to understand fully the terms of the exchange offer and the new notes.

#### **OUR COMPANY**

#### General

Alere Inc. enables individuals to take charge of improving their health and quality of life at home by developing new capabilities in near-patient diagnosis, monitoring and health management. Our global leading products and services, as well as our new product development efforts, focus on cardiology, women s health, infectious disease, oncology and drugs of abuse. Our business is organized into three major reportable segments: professional diagnostics, health management and consumer diagnostics. Through our professional diagnostics segment, we develop, manufacture and market an extensive array of innovative rapid diagnostic test products and other in vitro diagnostic tests to medical professionals and laboratories for detection of infectious diseases, cardiac conditions, drugs of abuse and pregnancy. Our health management segment provides comprehensive, integrated programs and services focused on wellness, disease and condition management, productivity enhancement and informatics, all designed to reduce health-related costs and enhance the health and quality of life of the individuals we serve. Our consumer diagnostic segment consists primarily of manufacturing operations related to our role as the exclusive manufacturer of products for SPD Swiss Precision Diagnostics, or SPD, our 50/50 joint venture with The Procter & Gamble Company, or P&G. SPD holds a leadership position in the worldwide over-the-counter pregnancy and fertility/ovulation test market. We have grown our businesses by leveraging our strong intellectual property portfolio and making selected strategic acquisitions. Our products are sold in approximately 150 countries through our direct sales force and an extensive network of independent global distributors.

Alere Inc. is a Delaware corporation. Our principal executive offices are located at 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453 and our telephone number is (781) 647-3900. Our website is www.alere.com. The information found on our website is not part of this prospectus.

#### Additional Information

For a more complete description of our business, you should refer to our Annual Report on Form 10-K/A for our fiscal year ended December 31, 2009 and to our Quarterly Report on Form 10-Q for our fiscal quarter ended September 30, 2010.

1

#### SUMMARY OF THE TERMS OF THE EXCHANGE OFFER

On September 21, 2010, we completed the private offering of \$400.0 million aggregate principal amount of old notes. As part of that offering, we entered into a registration rights agreement with Jefferies & Company, Inc., Goldman, Sachs & Co. and Citigroup Global Markets Inc., as representatives of the initial purchasers of the old notes in which we agreed, among other things, to deliver this prospectus to you and to conduct an exchange offer for the old notes. Below is a summary of the exchange offer.

**Old Notes** 

8.625% Senior Subordinated Notes due 2018 that were issued on September 21, 2010.

**New Notes** 

Up to \$400.0 million aggregate principal amount of our 8.625% Senior Subordinated Notes due 2018. The terms of the new notes are identical in all material respects to the terms of the old notes, except that the terms with respect to transfer restrictions, registration rights and payments of additional interest that relate to the old notes will be inapplicable to the new notes, and the new notes will bear different CUSIP and ISIN numbers than the old notes. After payment of the unpaid additional interest that has accrued on the old notes, if any, the additional interest provisions relating to the old notes will not apply. The new notes will be issued under and governed by the indenture dated May 12, 2009, between Alere Inc., as issuer, and U.S. Bank National Association, as trustee, as supplemented by a ninth supplemental indenture dated September 21, 2010, among Alere Inc., as issuer, the guarantors named therin, as guarantors, and U.S. Bank National Association, as trustee, and as may be further supplemented from time to time, under which we issued the old notes. which we refer to in this prospectus as the indenture. The new notes and the old notes will be treated as a single class of notes under the indenture.

The Exchange Offer

We are offering to exchange our old notes for a like amount of new notes in minimum denominations of \$2,000 and integral multiples of \$1,000. In order to be exchanged, an old note must be properly tendered and accepted. All old notes that are validly tendered and not withdrawn will be exchanged. As of the date of this prospectus, there is \$400.0 million aggregate principal amount of old notes outstanding. We will issue new notes promptly after the expiration of the exchange offer.

**Expiration Date and Time** 

The exchange offer will expire at 5:00 p.m., New York City time, on , 2011 unless we extend the exchange offer. If for any reason, including an extension by us, the exchange offer is not consummated on or before June 18, 2011, we may be required to pay additional interest on the old notes.

**Conditions to the Exchange Offer** 

The exchange offer is subject to certain conditions, some of which may be waived by us. See The Exchange Offer Conditions to the Exchange Offer for information regarding the conditions to the exchange offer.

**Procedures for Tendering Old Notes** 

The old notes were issued as global securities. Beneficial interests that are held by direct or indirect participants in The Depository Trust Company,

or DTC, are shown on, and transfers of the old notes can be made only through, records maintained in book-entry form by DTC with respect to its participants.

2

If you are a holder of old notes held in book-entry form and you wish to tender your old notes pursuant to the exchange offer, you must transmit to the exchange agent, before the expiration time either:

a written or facsimile copy of an executed letter of transmittal and all other required documents to the address set forth on the cover page of the letter of transmittal; or

a computer-generated message transmitted by means of DTC s Automated Tender Offer Program system in which you acknowledge and agree to be bound by the terms of the letter of transmittal and which, when received by the exchange agent, forms a part of a confirmation of book-entry transfer.

The exchange agent must also receive before the expiration time a timely confirmation of the book-entry transfer of your old notes into the exchange agent s account at DTC, in accordance with the procedures described for book-entry transfer in this prospectus under the heading The Exchange Offer Procedures for Tendering Old Notes.

By tendering your old notes, you will represent to us in writing that, among other things:

you are not an affiliate (as defined in Rule 405 under the Securities Act) of us or any subsidiary guarantor of the new notes, or if you are an affiliate, you will comply with the registration and prospectus delivery requirements under the Securities Act to the extent applicable;

you are not participating, do not intend to participate and have no arrangement or understanding with any person to participate in the distribution (within the meaning of the Securities Act) of the new notes in violation of the provisions of the Securities Act;

you will receive the new notes in the ordinary course of your business;

if you are not a broker-dealer, you are not engaged in, and do not intend to engage in, a distribution of new notes; and

if you are a broker-dealer that will receive new notes for your own account in exchange for old notes acquired as a result of market-making or other trading activities, which we refer to as a participating broker-dealer, you will deliver a prospectus in connection with any resale of such new notes.

If any of these conditions are not satisfied and you transfer any new notes issued to you in the exchange offer without delivering a prospectus meeting the requirements of the Securities Act or without an exemption from registration from these requirements, you may incur liability under

the Securities Act. We will not assume, nor will we indemnify you against, any such liability.

## **Special Procedures for Beneficial Owners**

If you are the beneficial owner of book-entry interests in outstanding notes and your name does not appear on a security position

3

#### **Table of Contents**

listing of DTC as the holder of those book-entry interests or you own a beneficial interest in outstanding old notes that are registered in the name of a broker, dealer, commercial bank, trust company or other nominee and you wish to tender, you should contact the registered holder promptly and instruct the registered holder to tender on your behalf.

If you are a beneficial owner who wishes to tender on the registered holder s behalf, prior to completing and executing the letter of transmittal and delivering the old notes, you must either make appropriate arrangements to register ownership of the old notes in your name or obtain a properly completed bond power from the registered holder. The transfer of registered ownership may take considerable time. See The Exchange Offer Procedures for Tendering Old Notes.

#### **Guaranteed Delivery Procedures**

If you wish to tender your old notes in the exchange offer but the required documentation cannot be completed by the expiration time or the procedures for book-entry transfer cannot be completed on a timely basis, you must tender your old notes according to the guaranteed delivery procedures described in The Exchange Offer Procedures for Tendering Old Notes Guaranteed Delivery.

#### **Effect of Not Tendering**

Old notes that are not tendered or that are tendered but not accepted will, following the completion of the exchange offer, continue to be subject to the existing restrictions on transfer of the old notes.

The trading market for old notes not exchanged in the exchange offer may be significantly more limited after the exchange offer. Therefore, if your old notes are not tendered and accepted in the exchange offer, it may be more difficult for you to sell or transfer your unexchanged old notes.

Furthermore, you will not generally be able to require us to register your old notes under the Securities Act and you will not be able to resell, offer to resell or otherwise transfer your old notes unless they are registered under the Securities Act or unless you resell, offer to resell or otherwise transfer them under an exemption from the registration requirements of, or in a transaction not subject to, the Securities Act.

#### **Broker-Dealers**

Each broker-dealer that receives new notes for its own account in connection with the exchange offer must acknowledge that it will deliver a prospectus in connection with any resale of such new notes. This prospectus, as it may be amended or supplemented from time to time, may be used by a broker-dealer in connection with resales of new notes received in exchange for old notes acquired by such broker-dealer as a result of market-making activities or other trading activities. We have agreed that, for a period ending upon the earlier of the 45th day after the date of effectiveness of the registration statement of which this prospectus forms a part or such earlier time as such broker-dealers no longer own any old notes, unless such period is extended pursuant to the registration rights agreement, we will make this prospectus, as amended or supplemented,

available to any broker-dealer for use in connection

4

with any such resale. See Plan of Distribution. The letter of transmittal delivered with this prospectus states that a broker-dealer, by acknowledging that it will deliver and by delivering a prospectus, will not be deemed to admit that it is an underwriter within the meaning of the Securities Act.

Any broker-dealer who acquired old notes directly from us may not rely on interpretations of the staff of the SEC to the foregoing effect and must instead comply with the registration requirements and prospectus delivery requirements of the Securities Act (including being named as a selling securityholder) in order to resell the old notes or the new notes.

Withdrawal Rights

You may withdraw your tender of old notes at any time before the expiration time. To withdraw, the exchange agent must receive a notice of withdrawal at its address indicated under The Exchange Offer Exchange Agent before the expiration time. We will return to you, without charge, promptly after the expiration or termination of the exchange offer any old notes that you tendered but that were not accepted for exchange or that you tendered and withdrew prior to the expiration time.

**Interest Payments on the New Notes** 

The new notes will bear interest from the later of September 21, 2010 (the date on which the old notes were originally issued) or the most recent date through which interest has been paid on the old notes (if any). If your old notes are accepted for exchange, then you will receive interest on the new notes (including any accrued but unpaid additional interest on the old notes) and not on the old notes.

**Registration Rights Agreement** 

In connection with the offering of the old notes, we and the guarantor subsidiaries and Jefferies & Company, Inc., Goldman, Sachs & Co. and Citigroup Global Markets Inc., as representatives of the initial purchasers in the offering, entered into a registration rights agreement that granted the holders of the old notes issued in the offering certain exchange and registration rights. Specifically, in the registration rights agreement, we agreed to file, on or before February 18, 2011, the registration statement of which this prospectus forms a part with respect to a registered offer to exchange the old notes for the new notes. We also agreed to use our commercially reasonable efforts to have this registration statement declared effective by the SEC on or before May 19, 2011. We also agreed to use our commercially reasonable efforts to consummate the exchange offer on or before June 18, 2011. If we fail to fulfill any of these obligations under the registration rights agreement, additional interest will accrue on the old notes at a rate of 0.25% per annum for the first 90-day period immediately following failure to meet any of the deadlines listed above. The amount of the additional interest will increase by an additional 0.25% per annum with respect to each subsequent 90-day period up to a maximum amount of additional interest of 1.00% per annum, from and including the date on which any of the deadlines listed above were not met to, but excluding, the earlier of (1) the date on which all registration defaults have been cured or (2) the date on which all of the old

5

#### **Table of Contents**

notes otherwise become freely transferable by holders other than affiliates of us or any guarantor subsidiary without further registration under the

Securities Act.

**Tax Consequences** Your exchange of old notes for new notes will not be treated as a taxable

exchange for United States federal income tax purposes. See Material

United States Federal Income Tax Consequences.

**Accounting Treatment** The new notes will be recorded at the same carrying value as the old

notes, and we will not recognize any gain or loss from the exchange offer for accounting purposes. See The Exchange Offer Accounting Treatment.

**Acceptance of Old Notes and Delivery** 

of New Notes

Subject to the conditions stated in The Exchange Offer Conditions to the Exchange Offer, we will accept for exchange any and all old notes that are properly tendered and not withdrawn in the exchange offer at or before the expiration time. The new notes issued pursuant to this exchange offer will be delivered promptly following the expiration time. See The Exchange

Offer Procedures for Tendering Old Notes.

**Exchange Agent** We have appointed U.S. Bank National Association as the exchange agent

for the exchange offer. The mailing address and telephone number of the exchange agent are: U.S. Bank National Association, West Side Flats Operations Center, 60 Livingston Avenue, Mail Station EP-MN-WS2N, St. Paul, MN 55107-2292, Attention: Brandi Steward, 651-495-4738. See

The Exchange Offer Exchange Agent.

**Fees and Expenses**We will pay all expenses related to this exchange offer. See The Exchange

Offer Fees and Expenses.

**Use of Proceeds**We will not receive any cash proceeds from the issuance of the new notes.

In consideration for issuing the new notes in exchange for old notes as described in this prospectus, we will receive old notes of like principal amount. The old notes surrendered in exchange for the new notes will be

retired and canceled.

#### **Risk Factors**

You should carefully consider all information in this prospectus and the documents incorporated by reference herein. In particular, you should evaluate the specific risk factors set forth in the section entitled Risk Factors in this prospectus for a discussion of risks relating to our business and an investment in the new notes.

6

#### SUMMARY OF TERMS OF THE NEW NOTES

The following summary describes the principal terms of the new notes. The following description is subject to important limitations and exceptions. The Description of New Notes section of this prospectus contains a more detailed description of the new notes than this summary section.

**Issuer** 

Alere Inc., a Delaware corporation.

**Notes Offered** 

Up to \$400.0 million aggregate principal amount of our 8.625% Senior Subordinated Notes due 2018. The terms of the new notes are identical in all material respects to the terms of the old notes, except that the terms with respect to transfer restrictions, registration rights and payments of additional interest that relate to the old notes will be inapplicable to the new notes, and the new notes will bear different CUSIP and ISIN numbers than the old notes. After payment of the unpaid additional interest that has accrued on the old notes, if any, the additional interest provisions relating to the old notes will not apply. The new notes will be issued under and governed by the indenture dated May 12, 2009, between Alere Inc., as issuer, and U.S. Bank National Association, as trustee, as supplemented by a ninth supplemental indenture dated September 21, 2010, among Alere Inc., as issuer, the guarantors named therin, as guarantors, and U.S. Bank National Association, as trustee, and as may be further supplemented from time to time, under which we issued the old notes, which we refer to in this prospectus as the indenture. The new notes and the old notes will be treated as a single class of notes under the indenture.

**Maturity Date** 

October 1, 2018.

**Interest** 

8.625% per annum, payable semi-annually on April 1 and October 1 of each year, commencing April 1, 2011. Interest will accrue from the most recent date to which interest has been paid on the old notes.

**Optional Redemption** 

We may, at our option, redeem the 2010 senior subordinated notes, in whole or part, at any time on or after October 1, 2014, at the redemption prices described in Description of New Notes Redemption Optional Redemption plus accrued and unpaid interest to (but excluding) the redemption date.

Optional Redemption After Certain Equity Offerings

At any time (which may be more than once) until October 1, 2013, we can choose to redeem up to 35% of the 2010 senior subordinated notes, including any additional notes that may be issued under the indenture, with money that we raise in certain equity offerings, so long as:

we pay 108.625% of the face amount of the applicable 2010 senior subordinated notes, plus accrued and unpaid interest to (but excluding) the redemption date;

we redeem the applicable 2010 senior subordinated notes within 90 days of completing such equity offering; and

at least 65% of the aggregate principal amount of the 2010 senior subordinated notes (including any additional notes that may be issued under the indenture) remains outstanding afterwards. See

7

Description of New Notes Redemption Redemption with Proceeds from Equity Offerings.

#### **Make-Whole Redemption**

Prior to October 1, 2014, we may redeem some or all of the new notes by the payment of a make-whole premium described under Description of New Notes Redemption Make-whole Redemption, plus accrued and unpaid interest to (but excluding) the redemption date.

#### **Change of Control**

If a change of control occurs, subject to certain conditions, we must give holders of the new notes an opportunity to sell the new notes to us at a purchase price of 101% of the principal amount of the new notes, plus accrued and unpaid interest to (but excluding) the date of the purchase. The credit agreements governing our secured credit facilities prohibit us from repurchasing any of the new notes in connection with a change of control before the repayment in full of all amounts outstanding under the secured credit facilities. If a change of control were to occur, we may be unable to repurchase any of the new notes due to this or similar prohibitions or because we do not have adequate funds. See Description of New Notes Change of Control.

#### Guarantees

The payment of the principal, premium and interest on the new notes is or will be fully and unconditionally guaranteed, jointly and severally, on a senior subordinated basis by, subject to certain exceptions, all of our current and future domestic subsidiaries that guarantee certain other of our indebtedness. A guarantee may be released if we dispose of the guarantor subsidiary, if the guarantor subsidiary ceases to guarantee certain other indebtedness of ours or any of our other subsidiaries, or if it is designated as an unrestricted subsidiary. See Description of New Notes Guarantees of the Notes.

#### Ranking

The new notes will be our general unsecured senior subordinated obligations and will be:

junior in right of payment to all of our existing and future senior indebtedness, including indebtedness arising under our secured credit facilities and our 7.875% senior notes due 2016, which we refer to as our senior notes;

pari passu in right of payment with all of our existing and future senior subordinated indebtedness, including indebtedness arising under our old notes, our 9.00% senior subordinated notes due 2016 that we issued on May 12, 2009, which we refer to as our 2009 senior subordinated notes, and indebtedness arising under our 3.00% senior subordinated convertible notes due 2016 that we issued on May 14, 2007, which we refer to as our 2007 senior subordinated convertible notes;

senior in right of payment to all of our existing and future indebtedness that is, by its terms, subordinated in right of payment to the new notes;

unconditionally guaranteed on a senior subordinated basis by the guarantor subsidiaries;

8

#### **Table of Contents**

effectively subordinated to all of our existing and future secured indebtedness, including indebtedness arising under our secured credit facilities, to the extent of the value of the assets securing such indebtedness; and

structurally subordinated to all existing and future obligations of each of our subsidiaries that does not guarantee the new notes.

See Description of New Notes Ranking of the Notes and the Guarantees and Description of New Notes Subordination of the Notes.

The guarantees will be general unsecured senior subordinated obligations of the guarantor subsidiaries and will be:

junior in right of payment to all existing and future senior indebtedness of the guarantor subsidiaries, including the guarantor subsidiaries—guarantees of the indebtedness arising under our secured credit facilities and our senior notes:

pari passu in right of payment with all existing and future senior subordinated indebtedness of the guarantor subsidiaries, including the guarantor subsidiaries guarantees of the indebtedness arising under our 2009 senior subordinated notes;

senior in right of payment to all existing and future indebtedness of the guarantor subsidiaries that is, by its terms, subordinated in right of payment to the guarantees;

effectively subordinated to all existing and future secured indebtedness of the guarantor subsidiaries, including the guarantor subsidiaries—guarantees of the indebtedness arising under our secured credit facilities, to the extent of the value of the assets securing such indebtedness; and

structurally subordinated to all existing and future obligations of each of our subsidiaries that does not guarantee the new notes.

See Description of New Notes Ranking of the Notes and the Guarantees,
Description of New Notes Subordination of the Notes and Description of
New Notes Subordination of the Guarantees of the Notes.

As of September 30, 2010, we had approximately \$1.4 billion in aggregate principal amount of senior indebtedness outstanding and approximately \$1.2 billion in aggregate principal amount of secured indebtedness outstanding, including approximately \$1.2 billion in aggregate principal amount of indebtedness outstanding under our secured credit facilities.

If we or our subsidiaries engage in asset sales, we generally must either invest the net cash proceeds from such sales in our business within a

**Asset Sale Proceeds** 

period of time, repay senior indebtedness or make an offer to purchase a principal amount of the 2010 senior subordinated notes (including any additional notes issued under the indenture) equal to the excess net cash proceeds, subject to certain exceptions. The purchase price of the 2010 senior subordinated notes will be 100% of their principal amount, plus accrued and unpaid interest.

9

#### **Table of Contents**

See Description of New Notes Certain Covenants Limitations on Asset Sales.

#### **Certain Covenants**

The indenture governing the new notes contains covenants that limit our ability and our restricted subsidiaries ability to, among other things:

incur additional debt;

pay dividends on our capital stock or redeem, repurchase or retire our capital stock or subordinated debt;

make certain investments;

create liens on our assets;

transfer or sell assets:

engage in transactions with our affiliates;

create restrictions on the ability of our subsidiaries to pay dividends or make loans, asset transfers or other payments to us;

issue capital stock of our subsidiaries;

engage in any business, other than our existing businesses and related businesses:

enter into sale and leaseback transactions;

incur layered indebtedness; and

consolidate or merge with any person (other than certain affiliates) or transfer all or substantially all of our assets or the aggregate assets of us and our subsidiaries.

These covenants are subject to important exceptions and qualifications, which are described under the caption Description of New Notes Certain Covenants.

#### **Covenant Suspension**

At any time that the new notes are rated investment grade, and subject to certain conditions, certain covenants contained in the indenture will be suspended. See Description of New Notes Certain Covenants.

**Book-Entry Form** 

Initially, the new notes will be represented by one or more global notes in definitive, fully registered form deposited with a custodian for, and registered in the name of, a nominee of The Depository Trust Company.

Illiquid Market

There can be no assurance as to the development or liquidity of any market for the new notes. At the time of the private offering of the old

notes, the initial purchasers of the old notes advised us that they intended to make a market for the old notes. However, they are not obligated to do so with respect to the new notes and may discontinue any such market-making activities at any time without notice.

**Transfer Restrictions** 

The old notes have not been registered under the Securities Act or any state securities laws and are subject to restrictions on transfer. The new notes have been registered under the Securities Act and are not subject to those restrictions.

10

#### RISK FACTORS

You should carefully consider the following risk factors as well as the other information contained or incorporated by reference in this prospectus before deciding to tender your outstanding old notes in the exchange offer. The risks described below are not the only risks facing us. Additional risks and uncertainties not currently known to us or those we currently view to be immaterial may also materially and adversely affect our business, financial condition or results of operations. Any of the following risks could materially and adversely affect our business, financial condition or results of operations. In such a case, you may lose all or part of your original investment. This prospectus contains or incorporates statements that constitute forward-looking statements regarding, among other matters, our intentions, beliefs or current expectations about our business. These forward-looking statements are subject to risks, uncertainties and assumptions, as further described in the section entitled Special Note Regarding Forward-Looking Statements.

#### **Risks Relating to Tendering Old Notes for New Notes**

There may be a limited or no trading market for the new notes, and you may not be able to sell them quickly or at the price that you paid.

The new notes are a new issue of securities and there is no established trading market for the new notes. We do not intend to apply for the new notes to be listed on any securities exchange or to arrange for quotation on any automated dealer quotation system. At the time of the private offering of the old notes, the initial purchasers advised us that they intended to make a market for the old notes. However, the initial purchasers are not obligated to do so with respect to the new notes and may discontinue any such market-making activities at any time without notice. In addition, the liquidity of the trading market in the new notes, if any, and any market price quoted for the new notes, may be adversely affected by changes in the overall market for high-yield securities and by changes in our financial performance or prospects or in the financial performance or prospects for companies in our industry generally. In addition, such market-making activities, if any, will be subject to limits imposed by the United States federal securities laws, and may be limited during the pendency of any shelf registration statement. As a result, there may be a limited or no active trading market for the new notes, which could negatively impact your ability to sell the new notes. In addition, if there is a limited or no active trading market for the new notes, the prices that you receive when you sell may not be favorable. Future trading prices of the new notes will depend on many factors, including:

our operating performance and financial condition;

our ability to complete the offer to exchange the old notes for the new notes;

the interest of securities dealers in making a market; and

the market for similar securities.

If you do not carefully follow the required procedures in order to exchange your old notes, you will continue to hold old notes subject to transfer restrictions, which will make it difficult for you to sell or otherwise transfer such old notes.

If the required procedures for the exchange of the old notes are not followed, you will continue to hold old notes, which are subject to transfer restrictions. The new notes will be issued in exchange for the old notes only after timely receipt by the exchange agent of a properly completed and executed letter of transmittal and all other required

documents. Therefore, if you wish to tender your old notes, you must allow sufficient time to ensure timely delivery. Neither we nor the exchange agent has any duty to notify you of defects or irregularities with respect to tenders of old notes for exchange. Any holder of old notes who tenders in the exchange offer for the purpose of participating in a distribution of the new notes will be required to comply with the registration and prospectus delivery requirements of the Securities Act in connection with any resale transaction. Each broker or dealer that receives new notes for its own account in exchange for old notes that were acquired in market-making or other trading activities must acknowledge that it will deliver a prospectus in connection with any resale of the new notes. See Plan of Distribution.

11

#### **Table of Contents**

In certain instances, failure of participants in the exchange offer to deliver a prospectus in connection with transfers of the new notes could result in liability under the Securities Act.

Based on no-action letters issued by the staff of the SEC, we believe that certain holders may offer for resale, resell or otherwise transfer the new notes without compliance with the registration and prospectus delivery requirements of the Securities Act. However, in some instances described in this prospectus under The Exchange Offer, you will remain obligated to comply with the registration and prospectus delivery requirements of the Securities Act (including being named a selling securityholder) to transfer your new notes. In these cases, if you transfer any new note without delivering a prospectus meeting the requirements of the Securities Act, you may incur liability under the Securities Act. We do not and will not assume, or indemnify you against, this liability.

#### **Risks Relating to Continued Ownership of Old Notes**

If you do not exchange old notes for new notes, transfer restrictions will continue and trading of the old notes may be difficult, which could result in a decrease in the value of the old notes.

The old notes have not been registered under the Securities Act and are subject to substantial restrictions on transfer. Old notes that are not tendered for exchange or are tendered but are not accepted will, following completion of the exchange offer, continue to be subject to existing restrictions on transfer. We do not expect to register the old notes under the Securities Act. You may not offer or sell the old notes unless they are registered under the Securities Act or the offer or sale is exempt from registration under the Securities Act and applicable securities laws. These continued transfer restrictions may make it difficult for you to sell or otherwise transfer old notes. See The Exchange Offer Consequences of Failure to Exchange.

The trading market for old notes could be limited, which could make it difficult for you to sell or otherwise transfer old notes and thereby result in a decrease in the value of the old notes.

There is a risk that an active trading market in the old notes will not exist, develop or be maintained following the consummation of the exchange offer. The trading market for old notes could become significantly more limited after the exchange offer as a result of the anticipated reduction in the amount of old notes outstanding upon consummation of the exchange offer. Therefore, if your old notes are not exchanged for new notes in the exchange offer, it may become more difficult for you to sell or otherwise transfer your old notes. This reduction in liquidity may in turn reduce the market price, and increase the price volatility, of the old notes.

#### Risks Relating to Our Debt, Including the New Notes

Our business has substantial indebtedness, which could, among other things, make it more difficult for us to satisfy our debt obligations, require us to use a large portion of our cash flow from operations to repay and service our debt or otherwise create liquidity problems, limit our flexibility to adjust to market conditions, place us at a competitive disadvantage and expose us to interest rate fluctuations.

We currently have, and will likely continue to have, a substantial amount of indebtedness. As of September 30, 2010, we had total debt outstanding of approximately \$2.4 billion, which included approximately \$943.7 billion in aggregate principal amount of indebtedness outstanding under our senior secured credit facility, \$250.0 million in aggregate principal amount of indebtedness outstanding under our junior secured credit facility, which we refer to, together with the senior secured credit facility, as our secured credit facilities, \$400.0 million in aggregate principal amount of indebtedness under our outstanding old notes, \$250.0 million in aggregate principal amount of indebtedness under our outstanding 2009 senior subordinated notes, and \$150.0 million in aggregate principal amount of indebtedness under our outstanding

2007 senior subordinated convertible notes.

12

#### **Table of Contents**

Our substantial indebtedness could affect our future operations in important ways. For example, it could:

make it more difficult to satisfy our obligations under the 2010 senior subordinated notes, the senior notes, the 2009 senior subordinated notes, the 2007 senior subordinated convertible notes, our secured credit facilities and our other debt-related instruments;

require us to use a large portion of our cash flow from operations to pay principal and interest on our indebtedness, which would reduce the amount of cash available to finance our operations and service obligations, to delay or reduce capital expenditures or the introduction of new products and/or to forego business opportunities, including acquisitions, research and development projects or product design enhancements:

limit our flexibility to adjust to market conditions, leaving us vulnerable in a downturn in general economic conditions or in our business and less able to plan for, or react to, changes in our business and the industries in which we operate;

impair our ability to obtain additional financing;

place us at a competitive disadvantage compared to our competitors that have less debt; and

expose us to fluctuations in the interest rate environment with respect to our indebtedness that bears interest at variable rates.

We expect to obtain the money to pay our expenses and to pay the principal and interest on the 2010 senior subordinated notes, the senior notes, the 2009 senior subordinated notes, the 2007 senior subordinated convertible notes, our secured credit facilities and our other indebtedness from cash flow from our operations and potentially from other debt or equity offerings. Accordingly, our ability to meet our obligations depends on our future performance and capital raising activities, which will be affected by financial, business, economic and other factors. We will not be able to control many of these factors, such as economic conditions in the markets in which we operate and pressure from competitors. We cannot be certain that our cash flow will be sufficient to allow us to pay principal and interest on our debt, including the new notes, and meet our other obligations. If our cash flow and capital resources prove inadequate, we could face substantial liquidity problems and might be required to dispose of material assets or operations, restructure or refinance our debt, including the new notes, seek additional equity capital or borrow more money. We cannot guarantee that we will be able to do so on acceptable terms. In addition, the terms of existing or future debt agreements, including the credit agreements governing our secured credit facilities and the indentures governing the 2010 senior subordinated notes, the senior notes, the 2009 subordinated notes and the 2007 senior subordinated convertible notes, may restrict us from adopting any of these alternatives.

## Despite our current indebtedness levels, we may incur substantially more indebtedness. This could further increase the risks associated with our leverage.

We may incur substantial additional indebtedness in the future. The agreements governing our indebtedness, including the credit agreements governing our secured credit facilities and the indentures governing the 2010 senior subordinated notes, the senior notes, the 2009 senior subordinated notes and the 2007 senior subordinated convertible notes, permit us, subject to certain limitations, to incur additional indebtedness, which may be substantial. If new indebtedness is added to our current levels of indebtedness, the related risks that we now face could intensify.

The agreements governing our indebtedness subject us to various restrictions that may limit our ability to pursue business opportunities.

The agreements governing our indebtedness, including the credit agreements governing our secured credit facilities and the indentures governing the 2010 senior subordinated notes, the senior notes, the 2009 senior subordinated notes and the 2007 senior subordinated convertible notes, subject us to various restrictions on our ability to engage in certain activities, including, among other things, our ability to:

incur additional debt;

pay dividends or make distributions or repurchase or redeem our stock or subordinated debt;

13

#### **Table of Contents**

acquire other businesses;

make investments;

make loans to or extend credit for the benefit of third parties or their subsidiaries;

prepay indebtedness;

enter into transactions with affiliates;

raise additional capital;

make capital or finance lease expenditures;

dispose of or encumber assets; and

consolidate, merge or sell all or substantially all of our assets.

These restrictions may limit or restrict our cash flow and our ability to pursue business opportunities or strategies that we would otherwise consider to be in our best interests.

Our secured credit facilities contain certain financial covenants that we may not satisfy, which, if not satisfied, could result in the acceleration of the amounts due under our secured credit facilities and the limitation of our ability to borrow additional funds in the future.

The agreements governing our secured credit facilities subject us to various financial and other restrictive covenants with which we must comply on an ongoing or periodic basis. These include covenants pertaining to maximum consolidated leverage ratios, minimum consolidated interest coverage ratios and limits on capital expenditures. If we violate any of these covenants, we may suffer a material adverse effect. Most notably, our outstanding debt under our secured credit facilities could become immediately due and payable, our lenders could proceed against any collateral securing such indebtedness and our ability to borrow additional funds in the future may be limited. Alternatively, we could be forced to refinance or renegotiate the terms and conditions of our secured credit facilities, including the interest rates, financial and restrictive covenants and security requirements of the secured credit facilities, on terms that may be significantly less favorable to us.

A default under any of the agreements governing our indebtedness could result in a default and acceleration of indebtedness under other agreements.

The agreements governing our indebtedness, including the credit agreements governing our secured credit facilities and the indentures governing the 2010 senior subordinated notes, the senior notes, the 2009 senior subordinated notes and the 2007 senior subordinated convertible notes, contain cross-default provisions whereby a default under one agreement could result in a default and acceleration of our repayment obligations under other agreements. If a cross-default were to occur, we may not be able to pay our debts or borrow sufficient funds to refinance them. Even if new financing were available, it may not be on commercially reasonable terms or acceptable terms. If some or all of our indebtedness is in default for any reason, our business, financial condition and results of operations could be materially and adversely affected.

If we default on our obligations to pay our indebtedness, we may not be able to make payments on the new notes.

Any default under the agreements governing our indebtedness, including a default under our secured credit facilities, that is not waived by the required lenders, and the remedies sought by the holders of such indebtedness, could prevent us from paying principal, premium, if any, and interest on the new notes and substantially decrease the market value of the new notes. If we are unable to generate sufficient cash flow and are otherwise unable to obtain funds necessary to meet required payments of principal, premium, if any, and interest on our indebtedness, or if we otherwise fail to comply with the various covenants, including financial and operating covenants, in the instruments governing our indebtedness (including covenants in our secured credit facilities and the indentures governing the 2010 senior subordinated notes, the senior notes and the 2009 senior subordinated notes), we could be in default under the terms of the agreements governing such

14

#### **Table of Contents**

indebtedness. In the event of such default, the holders of such indebtedness could elect to declare all the funds borrowed thereunder to be due and payable, together with accrued and unpaid interest, the lenders under our secured credit facilities could elect to terminate their commitments thereunder, cease making further loans and institute foreclosure proceedings against our assets, and we could be forced into bankruptcy or liquidation. If our operating performance declines, we may need to obtain waivers from the required lenders under our secured credit facilities to avoid being in default. If we breach our covenants under our secured credit facilities and seek a waiver, we may not be able to obtain a waiver from the required lenders. If this occurs, we would be in default under our secured credit facilities, the lenders could exercise their rights, as described above, and we could be forced into bankruptcy or liquidation.

#### The new notes and the related guarantees are not secured by our assets or those of our guarantor subsidiaries.

The new notes and the related guarantees are our and our guarantor subsidiaries—general unsecured obligations and are effectively subordinated in right of payment to all of our and our guarantor subsidiaries—secured indebtedness and obligations, including secured obligations that are otherwise subordinated. Accordingly, our secured indebtedness and obligations, including secured obligations that are otherwise subordinated, would effectively be senior to the new notes to the extent of the value of the collateral securing that indebtedness.

As of September 30, 2010, we had approximately \$1.2 billion in aggregate principal amount of secured indebtedness outstanding, including approximately \$1.2 billion in aggregate principal amount of indebtedness outstanding under our secured credit facilities. Any additional borrowings pursuant to our existing or future credit facilities would also be secured indebtedness if incurred. Although the indenture governing the new notes contains limitations on the amount of additional indebtedness that we may incur, under certain circumstances the amount of such indebtedness could be substantial and, in any case, such indebtedness may be secured indebtedness. See Description of New Notes Certain Covenants Limitations on Additional Indebtedness.

# Your right to receive payments on the new notes and the related guarantees is subordinated to our and our guarantor subsidiaries senior debt.

The indebtedness evidenced by the new notes and the related guarantees are our senior subordinated obligations and those of our guarantor subsidiaries. The payment of the principal of and interest on the new notes and the payment of the related subsidiary guarantees are each subordinate in right of payment, as set forth in the indenture governing the new notes, to the prior payment in full of all of our senior indebtedness and obligations or the senior indebtedness and obligations of our subsidiary guarantors, as the case may be, including our obligations under, and the guarantee obligations of our guarantor subsidiaries with respect to, our secured credit facilities and our senior notes. Any future subsidiary guarantee of the new notes will be similarly subordinated to the senior indebtedness and obligations of such guarantor subsidiary.

As of September 30, 2010, we had approximately \$1.4 billion of senior debt outstanding, including approximately \$1.2 billion in aggregate principal amount of indebtedness outstanding under our secured credit facilities and \$250.0 million in aggregate principal amount of indebtedness outstanding under our senior notes. Any additional borrowings pursuant to our existing or future credit facilities would also be senior indebtedness if incurred. Although the indenture governing the notes contains limitations on the amount of additional indebtedness that we may incur, under certain circumstances the amount of such indebtedness could be substantial and, in any case, such indebtedness may be senior indebtedness. See Description of Notes Certain Covenants Limitations on Additional Indebtedness.

Because the new notes are unsecured and because of the subordination provisions of the new notes, in the event of our bankruptcy, liquidation or dissolution, or that of any subsidiary guarantor, our assets and the assets of the subsidiary guarantors would be available to pay obligations under the new notes only after all payments had been made on our

and the subsidiary guarantors senior indebtedness, including under our secured credit facilities and our senior notes. We cannot assure you that, after all these payments have been

15

#### **Table of Contents**

made, sufficient assets will remain to make any payments on the notes, including payments of interest when due. These subordination provisions may cause you to recover less ratably than our other creditors in a bankruptcy, liquidation or dissolution. In addition, all payments on the notes and the related guarantees will be prohibited in the event of a payment default on certain senior indebtedness as designated under the indenture governing the new notes, including our secured credit facilities, and may be prohibited for up to 180 days in the event of non-payment defaults on certain of our senior indebtedness, including the secured credit facilities. See Description of Notes Ranking of the Notes and the Guarantees and Description of Notes Subordination of the Notes.

# Your right to receive payment on the new notes will be structurally subordinated to the obligations of our non-guarantor subsidiaries.

Some of our existing and future domestic subsidiaries will guarantee our obligations under the new notes. However, our foreign subsidiaries and our other domestic subsidiaries will not be required by the indenture to guarantee the new notes. Our non-guarantor subsidiaries are separate and distinct legal entities with no obligation to pay any amounts due pursuant to the new notes or the guarantees of the new notes or to provide us or the guarantor subsidiaries with funds for our payment obligations. Our cash flow and our ability to service our debt, including the new notes, depend in part on the earnings of our non-guarantor subsidiaries and on the distribution of earnings, loans or other payments to us by these subsidiaries. For the fiscal year ended December 31, 2009, our non-guarantor subsidiaries had net revenues of approximately \$630.7 million, or approximately 32.8% of our consolidated 2009 revenues, and operating income of approximately \$58.1 million, or approximately 39.8% of our consolidated 2009 operating income. For the nine months ended September 30, 2010, our non-guarantor subsidiaries had net revenues of approximately \$586.6 million, or approximately 37.2% of our consolidated revenues for that period, and operating income of approximately \$43.1 million, or approximately 52.5% of our consolidated operating income for that period. As of September 30, 2010, our non-guarantor subsidiaries had assets of approximately \$2.1 billion, or approximately 28.4% of our consolidated assets. These figures do not give pro forma effect to any acquisition we have made. Payments to us or a guarantor subsidiary by these non-guarantor subsidiaries will be contingent upon their earnings and their business considerations.

The new notes will be structurally subordinated to all current and future liabilities, including trade payables, of our subsidiaries that do not guarantee the new notes, and the claims of creditors of those subsidiaries, including trade creditors, will have priority as to the assets and cash flows of those subsidiaries. In the event of a bankruptcy, liquidation, dissolution or similar proceeding of any of the non-guarantor subsidiaries, holders of their liabilities, including their trade creditors, will generally be entitled to payment on their claims from assets of those subsidiaries before any assets are made available for distribution to us or our guarantor subsidiaries. As of September 30, 2010, the non-guarantor subsidiaries had approximately \$568.9 million of total indebtedness and other liabilities, including trade payables but excluding intercompany liabilities.

The lenders under our secured credit facilities will have the discretion to release the guarantors under the secured credit facilities in a variety of circumstances, which will cause those guarantors to be released from their guarantees of the new notes.

While any obligations under our secured credit facilities remain outstanding, any guarantee of the new notes may be released without action by, or consent of, any holder of the new notes or the trustee under the indenture governing the new notes if the relevant guarantor is no longer a guarantor of obligations under the secured credit facilities or certain other indebtedness. See Description of New Notes Guarantees of the Notes. The lenders under the secured credit facilities or such other indebtedness will have the discretion to release the guarantees under the secured credit facilities in a variety of circumstances. You will not have a claim as a creditor against any subsidiary that is no longer a guarantor of the new notes.

#### **Table of Contents**

If we undergo a change of control, we may not have the ability to raise the funds necessary to finance the change of control offer required by the indenture governing the new notes, which would violate the terms of the new notes.

Upon the occurrence of a change of control, as defined in the indenture governing the 2010 senior subordinated notes, holders of the 2010 senior subordinated notes will have the right to require us to purchase all or any part of such holders 2010 senior subordinated notes at a price equal to 101% of the principal amount thereof, plus accrued and unpaid interest, if any, to (but excluding) the date of purchase. The events that constitute a change of control under the indenture may also constitute:

a default under our secured credit facilities, which prohibit the purchase of the 2010 senior subordinated notes by us in the event of certain changes of control, unless and until our indebtedness under the secured credit facilities is repaid in full;

a change of control under the indentures governing our senior notes and our 2009 senior subordinated notes, which would give the holders of the senior notes and the holders of the 2009 senior subordinated notes the right to require us to purchase all or any part of such notes at a price equal to 101% of the principal amount thereof, plus accrued and unpaid interest, if any to (but excluding) the date of purchase; and

a fundamental change under the indenture governing our 2007 senior subordinated convertible notes, which would give the holders of the 2007 senior subordinated convertible notes the right to require us to purchase all or any part of such notes at a price equal to 100% of the principal amount thereof, plus accrued and unpaid interest, if any, to (but excluding) the date of purchase.

There can be no assurance that either we or our guarantor subsidiaries would have sufficient financial resources available to satisfy all of our or their obligations under the new notes or the related guarantees, our secured credit facilities or the related guarantees, our old notes or the related guarantees, our senior notes or the related guarantees, our 2009 senior subordinated notes or the related guarantees, or our 2007 senior subordinated convertible notes in the event of a change of control. Our failure to purchase the 2010 senior subordinated notes as required under the indenture governing the 2010 senior subordinated notes would result in a default under that indenture and under our secured credit facilities and could result in a default under the indentures governing the senior notes, the 2009 senior subordinated notes and the 2007 senior subordinated convertible notes, each of which could have material adverse consequences for us and the holders of the new notes. See Description of New Notes Change of Control.

The trading prices of the new notes will be directly affected by our ratings with major credit rating agencies, the prevailing interest rates being paid by companies similar to us, and the overall condition of the financial and credit markets.

The trading prices of the new notes in the secondary market will be directly affected by our ratings with major credit rating agencies, the prevailing interest rates being paid by companies similar to us, and the overall condition of the financial and credit markets. It is impossible to predict the prevailing interest rates or the condition of the financial and credit markets. Credit rating agencies continually revise their ratings for companies that they follow, including us. Any ratings downgrade could adversely affect the trading price of the new notes or the trading market for the new notes, to the extent a trading market for the new notes develops. The condition of the financial and credit markets and prevailing interest rates have fluctuated in the past and are likely to fluctuate in the future.

A subsidiary guarantee could be voided if it constitutes a fraudulent transfer under U.S. federal bankruptcy or similar state law, which would prevent the holders of the new notes from relying on that subsidiary to satisfy claims.

The new notes will be guaranteed by some of our domestic subsidiaries that are guarantors or borrowers under our secured credit facilities. The guarantees may be subject to review under U.S. federal bankruptcy law and comparable provisions of state fraudulent conveyance laws if a bankruptcy or another similar case or

17

#### **Table of Contents**

lawsuit is commenced by or on behalf of our or a guarantor subsidiary s unpaid creditors or another authorized party. Under these laws, if a court were to find that, at the time any guarantor subsidiary issued a guarantee of the new notes, either it issued the guarantee to delay, hinder or defraud present or future creditors, or it received less than reasonably equivalent value or fair consideration for issuing the guarantee and at the time:

it was insolvent or rendered insolvent by reason of issuing the guarantee;

it was engaged, or about to engage, in a business or transaction for which its remaining unencumbered assets constituted unreasonably small capital to carry on its business;

it intended to incur, or believed that it would incur, debts beyond its ability to pay as they mature; or

it was a defendant in an action for money damages, or had a judgment for money damages docketed against it if, in either case, after final judgment, the judgment is unsatisfied,

then the court could void the obligations under the guarantee, subordinate the guarantee of the new notes to other debt or take other action detrimental to holders of the new notes.

We cannot be sure as to the standard that a court would use to determine whether a guarantor subsidiary was solvent at the relevant time, or, regardless of the standard that the court uses, that the issuance of the guarantees would not be voided or that the guarantees would not be subordinated to other debt. If such a case were to occur, the guarantee could also be subject to the claim that, since the guarantee was incurred for our benefit, and only indirectly for the benefit of the guarantor subsidiary, the obligations of the applicable guarantor subsidiary were incurred for less than fair consideration. A court could thus void the obligations under the guarantee, subordinate the guarantee to the applicable guarantor subsidiary s other debt or take other action detrimental to holders of the new notes. If a court were to void a guarantee, you would no longer have a claim against the guarantor subsidiary. Sufficient funds to repay the new notes may not be available from other sources, including the remaining guarantor subsidiaries, if any. In addition, the court might direct you to repay any amounts that you already received from or are attributable to the guarantor subsidiary.

Each subsidiary guarantee contains a provision intended to limit the guarantor subsidiary s liability to the maximum amount that it could incur without causing the incurrence of obligations under its subsidiary guarantee to be a fraudulent transfer. This provision may not be effective to protect the subsidiary guarantees from being voided under fraudulent transfer law.

# Interest on the 2010 senior subordinated notes may not be deductible by us for United States federal income tax purposes.

The deductibility of interest is subject to many limitations under the Internal Revenue Code. We may not be able to deduct, in whole or in part, the interest on the 2010 senior subordinated notes. The availability of an interest deduction with respect to the interest on the 2010 senior subordinated notes was not determinative in our issuance of such notes.

# Certain covenants contained in the indenture will not be applicable during any period in which the new notes are rated investment grade.

The indenture governing the new notes will provide that certain covenants will not apply to us during any period in which the new notes are rated investment grade by both Standard & Poor s and Moody s and no default has otherwise occurred and is continuing under the indenture. The covenants that would be suspended include, among others, limitations on our and our restricted subsidiaries ability to pay dividends, incur additional indebtedness, sell certain

assets and enter into certain other transactions. Any actions that we take while these covenants are not in force will be permitted even if the new notes are subsequently downgraded below investment grade and such covenants are subsequently reinstated. There can be no assurance that the new notes will ever be rated investment grade, or that if they are rated investment grade, the new notes will maintain such ratings. See Description of New Notes Certain Covenants Suspension of Covenants.

18

#### **Table of Contents**

#### **Risks Relating to Our Business**

Disruptions in the capital and credit markets related to the current national and worldwide financial crisis, which may continue indefinitely or intensify, could adversely affect our results of operations, cash flows and financial condition, or those of our customers and suppliers.

The recent disruptions in the capital and credit markets may continue indefinitely or intensify, and adversely impact our results of operations, cash flows and financial condition, or those of our customers and suppliers. These disruptions could adversely affect our ability to draw on our bank revolving credit facility, which is dependent on the ability of the banks that are parties to the facility to meet their funding commitments. Those banks may not be able to meet their funding commitments to us if they experience shortages of capital and liquidity. Disruptions in the capital and credit markets as a result of uncertainty, changing or increased regulation, reduced alternatives or failures of significant financial institutions could adversely affect our access to liquidity needed to conduct or expand our businesses or conduct acquisitions or make other discretionary investments, as well as our ability to effectively hedge our currency exchange or interest rate risks. Such disruptions may also adversely impact the capital needs of our customers and suppliers, which, in turn, could adversely affect our results of operations, cash flows and financial condition.

We may not be able to satisfy our debt obligations upon a change of control or fundamental change, which could limit our opportunity to enter into a change of control or fundamental change transaction.

Upon the occurrence of a change of control, as defined in the indentures governing the 2010 senior subordinated notes, the senior notes and the 2009 senior subordinated notes, or a fundamental change or termination of trading, each as defined in the 2007 senior subordinated convertible notes, holders of the relevant notes will have the right to require us to purchase all or any part of such holders—notes at a price equal to either 100% (in the case of the 2007 senior subordinated convertible notes) or 101% (in the case of all other notes) of the principal amount thereof, plus accrued and unpaid interest, if any. The events that constitute a change of control, fundamental change or termination of trading under the relevant indentures may also constitute a default under our secured credit facilities, which currently prohibit us from purchasing any of the 2010 senior subordinated notes, any of the 2009 senior subordinated notes or any of the 2007 senior subordinated convertible notes in such events unless and until our indebtedness under the secured credit facilities is repaid in full.

There can be no assurance that either we or our guarantor subsidiaries will have sufficient financial resources available to satisfy all of our or their obligations under the 2010 senior subordinated notes, the senior notes, the 2009 senior subordinated notes, the 2007 senior subordinated convertible notes, and the secured credit facilities in the event of such a change of control, fundamental change or termination of trading. Our failure to purchase notes as required under any of the indentures governing the 2010 senior subordinated notes, the senior notes, the 2009 senior subordinated notes or the 2007 senior subordinated convertible notes would constitute a default under that indenture and under our secured credit facilities and could have material adverse consequences for us and holders of the notes.

Our acquisitions may not be profitable, and the integration of these businesses may be costly and difficult and may cause disruption to our business.

Since commencing activities in November 2001, we have acquired and integrated into our operations numerous businesses. Since the beginning of 2007, we have acquired and integrated, or are in the process of integrating, Laboratory Specialists of America, Inc.; Standard Diagnostics, Inc.; Free & Clear, Inc.; Concateno plc; certain assets of ACON Laboratories, Inc. and certain related entities, or the ACON second territory business; Alere Health LLC, formerly Matria Healthcare, Inc., or Matria; BBI Holdings Plc; Panbio Limited; Alere Health Systems, Inc., formerly Paradigm Health Systems, Inc.; Redwood Toxicology Laboratory, Inc.; Alere Medical, Inc.; HemoSense, Inc.;

Cholestech Corporation, or Cholestech; Alere San Diego, Inc., formerly Biosite Incorporated, or Biosite; and Instant Technologies, Inc., or Instant. We have also made a number of smaller acquisitions. The ultimate success of all of these acquisitions depends, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating these businesses or assets into

19

#### **Table of Contents**

our existing businesses. However, the successful integration of independent businesses or assets is a complex, costly and time-consuming process. The difficulties of integrating companies and acquired assets include, among others:

consolidating manufacturing, research and development operations and health management information technology platforms, where appropriate;

integrating newly acquired businesses or product lines into a uniform financial reporting system;

coordinating sales, distribution and marketing functions and strategies, including the integration of our current health management products and services;

establishing or expanding manufacturing, sales, distribution and marketing functions in order to accommodate newly-acquired businesses or product lines or rationalizing these functions to take advantage of synergies;

preserving the important licensing, research and development, manufacturing and supply, distribution, marketing, customer and other relationships;

minimizing the diversion of management s attention from ongoing business concerns;

coordinating geographically separate organizations; and

regulatory issues relating to the integration of acquisitions or of legacy entities.

We may not accomplish the integration of our acquisitions smoothly or successfully. The diversion of the attention of our management from current operations to integration efforts and any difficulties encountered in combining operations could prevent us from realizing the full benefits anticipated to result from these acquisitions and adversely affect our other businesses. Additionally, the costs associated with the integration of our acquisitions may be substantial. To the extent that we incur integration costs that are not anticipated when we finance our acquisitions, these unexpected costs could adversely impact our liquidity or force us to borrow additional funds. Ultimately, the value of any business or asset that we have acquired may not be greater than or equal to the purchase price of that business or asset.

If we choose to acquire or invest in new and complementary businesses, products or technologies rather than developing them internally, such acquisitions or investments could disrupt our business and, depending on how we finance these acquisitions or investments, could result in the use of significant amounts of cash.

Our success depends in part on our ability to continually enhance and broaden our product offerings in response to changing technologies, customer demands and competitive pressures. Accordingly, from time to time, we may seek to acquire or invest in businesses, products or technologies instead of developing them internally. Acquisitions and investments involve numerous risks, including:

the inability to complete the acquisition or investment;

disruption of our ongoing businesses and diversion of management attention;

difficulties in integrating the acquired entities, products or technologies;

difficulties in operating the acquired business profitably;

difficulties in transitioning key customer, distributor and supplier relationships;

difficulties in evaluating, integrating and retaining key management;

risks associated with entering markets in which we have no, or limited, prior experience; and unanticipated costs.

In addition, any future acquisitions or investments may result in:

issuances of dilutive equity securities, which may be sold at a discount to market price; use of significant amounts of cash;

20

#### **Table of Contents**

the incurrence of debt;

the assumption of significant liabilities, including litigation;

unfavorable financing terms;

large one-time expenses; and

the creation of intangible assets, including goodwill, the write-down of which may result in significant charges to earnings.

If we fail to complete strategic acquisitions or investments, our ability to meet our goals may be compromised and our future business prospects may be limited.

We may be unable to come to terms on, or complete, potential acquisitions or investments in businesses we believe to be of strategic importance. This may occur for many reasons, including but not limited to:

we may not be able to agree on terms and conditions which we believe are reasonable;

we may be out bid by another party or parties;

we may not be able to finance the purchase price;

we may not have enough available stock to use as consideration;

a competitor may come to an agreement to acquire a targeted business before we are able to; or

antitrust or other laws or regulations may prohibit the acquisition or prevent us from completing the acquisition or investment in a manner which we believe would benefit us.

#### Our joint venture transaction with P&G may not realize all of its intended benefits.

In connection with SPD, our 50/50 joint venture with P&G, we may experience the following, among other problems:

difficulties in integrating our corporate culture and business objectives with that of P&G into the joint venture;

diversion of our management s time and attention from other business concerns;

difficulties in retaining key employees who are necessary to manage the joint venture; or

difficulties in working with an entity based in Switzerland and thus remote or inconvenient to our Waltham, Massachusetts headquarters.

Moreover, because SPD is a 50/50 joint venture, we do not have complete control over its operations, including business decisions which may impact SPD s profitability.

For any of these reasons, or as a result of other factors, we may not realize the anticipated benefits of the joint venture and cash flow or profits derived from our ownership interest in SPD may be less than the cash flow or profits that

could have been derived had we retained the transferred assets and continued to operate the consumer diagnostics business ourselves. P&G retains an option to require us to purchase P&G s interest in SPD at fair market value during the 60-day period beginning on May 17, 2011. Moreover, certain subsidiaries of P&G have the right, at any time upon certain material breaches by us or our subsidiaries of our obligations under the joint venture documents, to acquire all of our interest in the joint venture at fair market value less damages.

## We may not be successful in conducting future joint venture transactions.

In addition to SPD, our 50/50 joint venture with P&G, we may enter into additional joint venture transactions in the future. We may experience unanticipated difficulties in connection with those joint venture

21

#### **Table of Contents**

transactions. We cannot assure you that any such joint venture transaction will be profitable or that we will receive any of the intended benefits of such a transaction.

If goodwill and/or other intangible assets that we have recorded in connection with our acquisitions of other businesses become impaired, we could have to take significant charges against earnings.

In connection with the accounting for our acquisitions we have recorded, or will record, a significant amount of goodwill and other intangible assets. Under current accounting guidelines, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other intangible assets has been impaired. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our reported results of operations in future periods.

We may experience manufacturing problems or delays due to, among other reasons, our volume, specialized processes or global operations, which could result in decreased revenue or increased costs.

Many of our manufacturing processes are complex and involve sensitive scientific processes, including unique and often proprietary antibodies which cannot be replicated or acquired through alternative sources without undue delay or expense. In addition, our manufacturing processes often require complex and specialized equipment which can be expensive to repair or replace with required lead times of up to a year. Also, our private label consumer diagnostics business relies on operational efficiency to mass produce products at low margins per unit. We also rely on numerous third parties to supply production materials and, in some cases, there may not be alternative sources immediately available.

In recent years we have shifted production of several of our products to our manufacturing facilities in China and closed less efficient and more expensive facilities elsewhere. We expect to continue to shift production to China and other lower cost facilities as part of our continuing efforts to reduce costs, improve quality and more efficiently serve targeted markets. Moving the production of products is difficult and involves significant risk. Problems establishing relationships with local materials suppliers; acquiring or adapting the new facility and its equipment to the production of new products; hiring, training and retaining personnel; and establishing and maintaining compliance with governmental regulations and industry standards can cause delays and inefficiencies, which could have a material negative impact on our financial performance. We also currently rely on a number of significant third-party manufacturers to produce certain of our professional diagnostics products. Any event which negatively impacts our manufacturing facilities, our manufacturing systems or equipment, or our contract manufacturers or suppliers, including, among others, wars, terrorist activities, natural disasters and outbreaks of infectious disease, could delay or suspend shipments of products or the release of new products or could result in the delivery of inferior products. Our revenues from the affected products would decline or we could incur losses until such time as we or our contract manufacturers are able to restore our or their production processes or we are able to put in place alternative contract manufacturers or suppliers.

Even though we carry business interruption insurance policies, we may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies.

We may experience difficulties that may delay or prevent our development, introduction or marketing of new or enhanced products or services.

We intend to continue to invest in product and technology development. The development of new or enhanced products or services is a complex and uncertain process. We may experience research and development, manufacturing, marketing and other difficulties that could delay or prevent our development, introduction or marketing of new products, services or enhancements. We cannot be certain that:

any of the products or services under development will prove to be effective in clinical trials; any products or services under development will not infringe on intellectual property rights of others;

22

#### **Table of Contents**

we will be able to obtain, in a timely manner or at all, regulatory approval to market any of our products or services that are in development or contemplated;

the products and services we develop can be manufactured or provided at acceptable cost and with appropriate quality; or

these products and services, if and when approved, can be successfully marketed.

The factors listed above, as well as manufacturing or distribution problems, or other factors beyond our control, could delay new product or service launches. In addition, we cannot assure you that the market will accept these products and services. Accordingly, there is no assurance that our overall revenue will increase if and when new products or services are launched.

If the results of clinical studies required to gain regulatory approval to sell our products are not available when expected, or do not demonstrate the anticipated safety and effectiveness of those potential products, we may not be able to sell future products and our sales could be adversely affected.

Before we can sell certain of our products, we must conduct clinical studies intended to demonstrate that our potential products are safe and effective and perform as expected. The results of these clinical studies are used as the basis to obtain regulatory approval from government authorities such as the Food and Drug Administration, or FDA. Clinical studies are experiments conducted using potential products and human patients having the diseases or medical conditions that the product is trying to evaluate or diagnose. Conducting clinical studies is a complex, time-consuming and expensive process. In some cases, we may spend several years completing certain studies.

If we fail to adequately manage our clinical studies, those clinical studies and corresponding regulatory approvals may be delayed or we may fail to gain approval for our potential product candidates altogether. Even if we successfully manage our clinical studies, we may not obtain favorable results and may not be able to obtain regulatory approval. If we are unable to market and sell our new products or are unable to obtain approvals in the timeframe needed to execute our product strategies, our business and results of operations would be materially and adversely affected.

If we are unable to obtain required clearances or approvals for the commercialization of our products in the United States, we may not be able to sell future products and our sales could be adversely affected.

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. Regulatory approval can be a lengthy, expensive and uncertain process, making the timing, cost and ability to obtain approvals difficult to predict. In addition, regulatory processes are subject to change, and new or changed regulations can result in increased costs and unanticipated delays.

In the United States, clearance or approval to commercially distribute new medical devices is received from the FDA through clearance of a Premarket Notification, or 510(k), or through approval of a Premarket Approval, or PMA. To receive 510(k) clearance, a new product must be substantially equivalent to a medical device first marketed in interstate commerce prior to May 1976. The FDA may determine that a new product is not substantially equivalent to a device first marketed in interstate commerce prior to May 1976 or that additional information is needed before a substantial equivalence determination can be made. A not substantially equivalent determination, or a request for additional information, could prevent or delay the market introduction of new products that fall into this category. As part of the clearance or approval process, if we intend to sell certain diagnostic tests for home use or for use by laboratories holding a Clinical Laboratory Improvement Amendments of 1988, or CLIA, Certificate of Waiver, including most physician office laboratories, the FDA must determine that our tests are simple with a low risk of error.

To establish this, we may be required to collect and submit data regarding the use and accuracy of the diagnostic product, which can involve significant time and expense. The FDA clearance process can be expensive, uncertain and lengthy. It generally takes from three to five months from submission to obtain 510(k) clearance, and from six to eighteen months from submission to obtain a PMA approval; however, it may take longer, and 510(k) clearance or

23

#### **Table of Contents**

PMA approval, or clearance or approval to market a test or device for use in the home or by CLIA-waived laboratories, may never be obtained.

Modifications or enhancements that could significantly affect safety or effectiveness, or constitute a major change in the intended use of the device, require new 510(k) or PMA submissions. We have made modifications to some of our products since receipt of initial 510(k) clearance or PMA. With respect to several of these modifications, we filed new 510(k)s describing the modifications and received FDA 510(k) clearance. We have made other modifications to some of our products that we believe do not require the submission of new 510(k)s or PMAs. The FDA may not agree with any of our determinations not to submit a new 510(k) or PMA for any of these modifications made to our products. If the FDA requires us to submit a new 510(k) or PMA for any device modification, we may be prohibited from marketing the modified products until the new submission is cleared by the FDA.

There is increased uncertainty due to impending changes to the 510(k) and PMA processes. These reforms may increase the time to receive clearance or approval. The uncertainty of the requirements for clearance or approval may result in cost increases.

We are also subject to applicable regulatory approval requirements of the foreign countries in which we sell products, which are costly and may prevent or delay us from marketing our products in those countries.

In addition to regulatory requirements in the United States, we are subject to the regulatory approval requirements for each foreign country to which we export our products. In the European Union, regulatory compliance requires affixing the CE mark to product labeling. Although our products are currently eligible for CE marking through self-certification, this process can be lengthy and expensive. In Canada, as another example, our products require approval by Health Canada prior to commercialization, along with International Standards Organization, or ISO, 13485/CMDCAS certification. It generally takes from three to six months from submission to obtain a Canadian Device License. Any changes in foreign approval requirements and processes may cause us to incur additional costs or lengthen review times of our products. We may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and any failure to do so may cause us to incur additional costs or prevent us from marketing our products in foreign countries, which may have a material adverse effect on our business, financial condition and results of operations.

Failure to comply with ongoing regulations applicable to our businesses may result in significant costs or, in certain circumstances, the suspension or withdrawal of previously obtained clearances or approvals.

Our businesses are extensively regulated by the FDA and other federal, state and foreign regulatory agencies. These regulations impact many aspects of our operations, including manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping. For example, our manufacturing facilities and those of our suppliers and distributors are, or can be, subject to periodic regulatory inspections. The FDA and foreign regulatory agencies may require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any product approvals that could restrict the commercial applications of those products. In addition, the subsequent discovery of previously unknown problems with a product may result in restrictions on the product, including withdrawal of the product from the market. We are also subject to routine inspection by the FDA and certain state agencies for compliance with the Quality System Regulation and Medical Device Reporting requirements in the United States and other applicable regulations worldwide, including but not limited to ISO requirements. CLIA extended federal oversight to many clinical laboratories, including certain of our drug testing laboratories in the United States, by requiring that they be certified to meet quality assurance, quality control and personnel standards. Laboratories also must undergo proficiency testing and are subject to inspections. Certain of our drug testing laboratories perform drug testing on employees of federal government contractors and certain other entities and are therefore regulated by SAMHSA, which has established detailed performance and quality standards

that laboratories must meet to be approved to perform drug testing on employees of federal government contractors and certain other entities. Certain portions of our health management business are subject to unique

24

#### **Table of Contents**

licensing or permit requirements. For example, we may be required to obtain certification to participate in governmental payment programs, such as state Medicaid programs, we may need an operating license in some states, and some states have established Certificate of Need programs regulating the expansion of healthcare operations. In addition, we believe certain of our health management services are educational in nature, do not constitute the practice of medicine or provision of healthcare, and thus do not require that we maintain federal or state licenses to provide such services. However, it is possible that federal or state laws regarding the provision of virtual or telephonic medicine could be revised or interpreted to include our services, or that other laws may be enacted which require licensure or otherwise relate to our health management services. In such event, we may incur significant costs to comply with such laws and regulations. In addition, we are subject to numerous federal, state and local laws relating to such matters as privacy, healthcare kickbacks and false claims, safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with these laws and regulations. If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products or injunctions against our distribution, termination of our service agreements by our customers, disgorgement of money, operating restrictions and criminal prosecution.

New federal or state laws may be enacted, or regulatory agencies may impose new or enhanced standards, that would increase our costs, as well as expose us to risks associated with non-compliance. In addition, the federal government has enacted the Genetic Information Non-discrimination Act of 2008, or GINA, and we may incur additional costs in assisting our customers with their efforts to comply with GINA while continuing to offer certain of our services.

### Healthcare reform legislation could adversely affect our revenue and financial condition.

The Patient Protection and Affordable Care Act of 2010 (as amended by the Health Care and Education Reconciliation Act of 2010), or the PPACA, makes comprehensive reforms at the federal and state level affecting the coverage and payment for healthcare services in the United States. These provisions include comprehensive health insurance reforms and expansion of coverage of the uninsured, and long-term payment reforms to Medicare, Medicaid and other government programs. In particular, federal legislation has significantly altered Medicare Advantage reimbursements by setting the federal benchmark payment closer to the payments in the traditional Medicare program. This change could reduce our revenues from the Medicare Advantage plans for which we perform services, although the effect on any particular plan, much less the impact on us, is impossible to predict. Effective January 1, 2013, the legislation includes a 2.3% excise tax on the sale of certain medical devices. Legislative provisions impose federal reporting requirements regarding payments or relationships between manufacturers of covered drugs, devices or biological or medical supplies and physicians, among others.

Legislative and regulatory bodies are likely to continue to pursue healthcare reform initiatives and may continue to reduce the funding of the Medicare and Medicaid programs, including Medicare Advantage, in an effort to reduce overall federal healthcare spending. The ultimate impact of all of the reforms in the PPACA, and its impact on us, is impossible to predict. If all of the reforms in the legislation are implemented, or if other reforms in the United States or elsewhere are adopted, those reforms may have an adverse effect on our financial condition and results of operations.

If we deliver products with defects, our credibility may be harmed, market acceptance of our products may decrease and we may be exposed to liability in excess of our product liability insurance coverage.

The manufacturing and marketing of professional and consumer diagnostics involve an inherent risk of product liability claims. For example, a defect in one of our diagnostic products may cause the product to report inaccurate information, such as a false positive result, a false negative result or an error message. In addition, our product development and production are extremely complex and could expose our products to defects. Any defects could harm

our credibility and decrease market acceptance of our products. In addition, our marketing of monitoring services may cause us to be subjected to various product liability claims, including, among others, claims that inaccurate monitoring results lead to injury or death. Potential product

25

#### **Table of Contents**

liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. In the event that we are held liable for a claim for which we are not indemnified, or for damages exceeding the limits of our insurance coverage, that claim could materially damage our business and financial condition.

#### The effect of market saturation may negatively affect the sales of our products, including our Triage BNP tests.

Our meter-based Triage BNP test, launched domestically in January 2001, was the first blood test available to aid in the detection of heart failure and benefited from a first-to-market position until the entry of direct competition in June 2003. As the acute care and initial diagnosis market segment for BNP testing in the U.S. hospital setting becomes saturated, unless we are able to successfully introduce new products into the market and achieve market acceptance of those products in a timely manner, we expect the growth rates of sales unit volume for our Triage BNP tests and average selling prices in 2010 and future periods to be lower than the growth rates and selling prices experienced over the past several years, which may adversely impact our product sales, gross margins and overall financial results. In addition, as the market for BNP testing matures and more competitive products become available, the average sales price for the Triage BNP tests is likely to decline.

### The health management business is a relatively new component of the overall healthcare industry.

The health management services provided by our Alere health management business and our subsidiaries Quality Assured Services, Inc. and Alere Home Monitoring, Inc, formerly Tapestry Medical, Inc., are relatively new components of the overall healthcare industry. Accordingly, our health management customers have not had significant experience in purchasing, evaluating or monitoring such services, which can result in a lengthy sales cycle. The success of our health management business depends on a number of factors. These factors include:

our ability to differentiate our health management services from those of our competitors;

the extent and timing of the acceptance of our services as a replacement for, or supplement to, traditional managed care offerings;

the effectiveness of our sales and marketing and engagement efforts with customers and their health plan participants;

our ability to sell and implement new and additional services beneficial to health plans and employers and their respective participants or employees;

our ability to achieve, measure and effectively communicate cost savings for health plans and employers through the use of our services; and

our ability to retain health plan and employee accounts as competition increases and as health plan customers may choose to provide health management services themselves.

Since the health management business is continually evolving, we may not be able to anticipate and adapt to the developing market. Moreover, we cannot predict with certainty the future growth rate or the ultimate size of the market.

Increasing health insurance premiums and co-pays may cause individuals to forgo health insurance and avoid medical attention, either of which may reduce demand for our products and services.

Health insurance premiums and co-pays have generally increased in recent years. Increased premiums may cause individuals to forgo health insurance, as well as medical attention. This may reduce demand for our point-of-care diagnostic products and also reduce the number of lives managed by our health management programs. Increased co-pays may cause insured individuals to forgo medical attention thereby reducing demand for our professional diagnostic tests, as well as revenues under certain health management programs.

26

#### **Table of Contents**

#### Our health management business may be adversely affected by cost reduction pressures among our customers.

Our customers continue to face cost reduction pressures that may cause them to curtail their use of, or reimbursement for, health management services, to negotiate reduced fees or other concessions or to delay payment. In addition, the loss of jobs due to the recent economic crisis may cause the number of lives we manage to decrease. These financial pressures could have an adverse impact on our business.

# Rising unemployment may negatively impact the collectability of uninsured accounts and patient due accounts and/or reduce total health plan populations.

Certain of our health management contracts provide reimbursement to us based on total relevant populations managed by health plans. As unemployment rates rise, certain of our revenues may be reduced under these contracts as managed lives may decrease. One of the primary collection risks of our health management business s accounts receivable relates to uninsured patient accounts and patient accounts for which the primary insurance carrier has paid the amounts covered by the applicable agreement, but patient responsibility amounts (deductibles and copayments) remain outstanding. As unemployment rates rise nationally, these uninsured and patient due accounts could make up a greater percentage of the health management business s accounts receivable. Deterioration in the collectability of these accounts could adversely affect the health management business s collection of accounts receivable, cash flows and results of operations.

# If we are unable to retain and negotiate favorable contracts with managed care plans, our revenues may be reduced.

The ability of our health management business to obtain favorable contracts with health maintenance organizations, preferred provider organizations and other managed care plans significantly affects the revenues and operating results of our health management business. The business s future success will depend, in part, on its ability to retain and renew its managed care contracts and to enter into new managed care contracts on terms favorable to us. If the health management business is unable to retain and negotiate favorable contracts with managed care plans, our revenues may be reduced.

#### A portion of our health management fees are contingent upon performance.

Some of our existing health management agreements contain savings or other guarantees, which provide that our revenues, or a portion of them, are contingent upon projected cost savings or other quality performance measures related to our health management programs. There is no guarantee that we will accurately forecast cost savings and clinical outcome improvements under our health management agreements or meet the performance criteria necessary to recognize potential revenues under the agreements. Additionally, untimely, incomplete or inaccurate data from our customers, or flawed analysis of such data, could have a material adverse impact on our ability to recognize revenues.

# If our costs of providing health management services increase, we may not be able to pass these cost increases on to our customers.

Many of our health management services are provided pursuant to long-term contracts that we may not be able to re-negotiate. If our costs increase, we may not be able to increase our prices, which would adversely affect results of operations. Accordingly, any increase in our costs could reduce our overall profit margin.

#### Demands of non-governmental payers may adversely affect our growth in revenues.

Our ability to negotiate favorable contracts with non-governmental payers, including managed care plans, significantly affects the revenues and operating results of our health management business. These non-governmental payers increasingly are demanding discounted fee structures, and the trend toward consolidation among non-governmental payers tends to increase their bargaining power over fee structures. Reductions in price increases or the amounts received from managed care, commercial insurance or other payers could have

27

#### **Table of Contents**

a material, adverse effect on the financial position and results of operations of our health management business.

# Our data management and information technology systems are critical to maintaining and growing our business.

Our businesses, and in particular our health management business, are dependent on the effective use of information technology and, consequently, technology failure or obsolescence may negatively impact our businesses. In addition, data acquisition, data quality control, data security and data analysis, which are a cornerstone of our health management programs, are intense and complex processes subject to error. Untimely, incomplete or inaccurate data, flawed analysis of such data or our inability to properly integrate, implement and update systems could have a material adverse impact on our business and results of operations. In particular, we are relying on our recently launched healthcare portal, Apollo, to provide the framework and supporting infrastructure for significantly enhanced future health management programs and to provide a competitive advantage. Apollo is a new and unproven system and may not provide these expected benefits or meet our needs or the needs of our customers or program participants.

### Our financial condition or results of operations may be adversely affected by international business risks.

We generate a significant percentage of our net revenue from outside the United States, and a significant number of our employees, including manufacturing, sales, support and research and development personnel, are located in foreign countries, including England, Scotland, Japan, China, Australia, Germany and Israel. Conducting business outside the United States subjects us to numerous risks, including:

increased costs or reduced revenue as a result of movements in foreign currency exchange rates;

decreased liquidity resulting from longer accounts receivable collection cycles typical of foreign countries;

lower productivity resulting from difficulties managing sales, support and research and development operations across many countries;

lost revenues or unexpected expenses resulting from difficulties associated with enforcing agreements and collecting receivables through foreign legal systems;

lost revenues or unexpected expenses due to disputes with third-party distributors of our products or from third parties claiming distribution rights to our products under foreign laws or legal systems;

lost revenues or unexpected expenses resulting from the imposition by foreign governments of trade protection measures;

higher cost of sales resulting from import or export licensing requirements;

lost revenues or other adverse effects as a result of economic or political instability in or affecting foreign countries in which we sell our products or operate; and

adverse effects resulting from changes in foreign regulatory or other laws affecting the sales of our products or our foreign operations.

Because our business relies heavily on foreign operations and revenues, changes in foreign currency exchange rates and our need to convert currencies may negatively affect our financial condition and results of operations.

Our business relies heavily on our foreign operations. Three of our five largest manufacturing operations are conducted outside the United States in Hangzhou and Shanghai, China and Matsudo, Japan, and we also have manufacturing operations in the United Kingdom, Australia, South Africa and Israel. We also have significant research and development operations in Jena, Germany and Stirling, Scotland, as well as in the United Kingdom, Australia and Israel. In addition, for the year ended December 31, 2009, approximately 31%

28

#### **Table of Contents**

of our net revenue was derived from sales outside the United States. Because of our foreign operations and foreign sales, we face exposure to movements in foreign currency exchange rates. Our primary exposures are related to the operations of our European and Asia Pacific subsidiaries and our manufacturing facilities in China and Japan. These exposures may change over time as business practices evolve and could result in increased costs or reduced revenue and could affect our actual cash flow.

Intense competition could reduce our market share or limit our ability to increase market share, which could impair the sales of our products and harm our financial performance.

The medical products industry is rapidly evolving, and developments are expected to continue at a rapid pace. Competition in this industry, which includes both our professional diagnostics and consumer diagnostics businesses, is intense and expected to increase as new products and technologies become available and new competitors enter the market. Our competitors in the United States and abroad are numerous and include, among others, diagnostic testing and medical products companies, universities and other research institutions.

Our future success depends upon maintaining a competitive position in the development of products and technologies in our areas of focus. Our competitors may:

develop technologies and products that are more effective than our products or that render our technologies or products obsolete or noncompetitive;

obtain patent protection or other intellectual property rights that would prevent us from developing potential products; or

obtain regulatory approval for the commercialization of our products more rapidly or effectively than we do.

Also, the possibility of patent disputes with competitors holding patent rights may limit or delay expansion possibilities for our diagnostic businesses and new product launches. In addition, many of our existing or potential competitors have or may have substantially greater research and development capabilities, clinical, manufacturing, regulatory and marketing experience and financial and managerial resources.

We could suffer monetary damages, incur substantial costs or be prevented from using technologies important to our products as a result of a number of pending legal proceedings.

We are involved in various legal proceedings arising out of our businesses. Because of the nature of our business, we may be subject at any particular time to commercial disputes, product liability claims, negligence claims or various other lawsuits arising in the ordinary course of our business, including infringement, distributor disputes, employment matters or investor matters, and we expect that this will continue to be the case in the future. Such lawsuits generally seek damages, sometimes in substantial amounts, for commercial or personal injuries allegedly suffered and can include claims for punitive or other special damages. An adverse ruling or rulings in one or more such lawsuits could, individually or in the aggregate, have a material adverse effect on our sales, operations or financial performance. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights. We cannot assure you that these lawsuits or any future lawsuits relating to our business will not have a material adverse effect on us.

The rights we rely upon to protect the intellectual property underlying our products may not be adequate, which could enable third parties to use our technology and would reduce our ability to compete in the market.

Our success will depend in part on our ability to develop or acquire commercially valuable patent rights and to protect our intellectual property. Our patent position is generally uncertain and involves complex legal and factual questions. The degree of present and future protection for our proprietary rights is uncertain and may be impacted by intellectual property law or legislation.

29

#### **Table of Contents**

The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

pending patent applications we have filed, or to which we have exclusive rights, may not result in issued patents or may take longer than we expect to result in issued patents;

claims of any patents which are issued may not provide meaningful protection;

our inability to develop additional proprietary technologies that are patentable or can otherwise be protected as trade secrets;

patents licensed or issued to us or our customers may not provide a competitive advantage;

other parties may challenge patents or patent applications licensed or issued to us or our customers;

patents issued to other companies may harm our ability to do business;

other companies may design around technologies we have patented, licensed or developed; and

all patents have a limited life, meaning at some point valuable patents will expire and we may lose the competitive advantage which they provide.

In addition to patents, we rely on a combination of trade secrets, non-disclosure agreements and other contractual provisions and technical measures to protect our intellectual property rights. Nevertheless, these measures may not be adequate to safeguard the technology underlying our products. If these measures do not protect our rights, third parties could use our technology and our ability to compete in the market would be reduced. In addition, employees, consultants and others who participate in the development of our products may breach their agreements with us regarding our intellectual property, and we may not have adequate remedies for the breach. We also may not be able to effectively protect our intellectual property rights in some foreign countries. For a variety of reasons, we may decide not to file for patent, copyright or trademark protection or prosecute potential infringements of our patents. Our trade secrets may also become known through other means not currently foreseen by us. Despite our efforts to protect our intellectual property, our competitors or customers may independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing on any of our intellectual property rights, or design around our proprietary technologies.

Claims by others that our products infringe on their proprietary rights could adversely affect our ability to sell our products and services and could increase our costs.

Substantial litigation over intellectual property rights exists in both the professional and consumer diagnostics industries. We expect that our products and services could be increasingly subject to third-party infringement claims, as the number of competitors grows and the functionality of products and technology in different industry segments overlaps. Third parties may currently have, or may eventually be issued, patents which our products and services or technology may infringe. Any of these third parties might make a claim of infringement against us. Any litigation could result in the expenditure of significant financial resources and the diversion of management s time and resources. In addition, litigation in which we are accused of infringement may cause negative publicity, have an impact on prospective customers, cause product delays, require us to develop non-infringing technology, make substantial payments to third parties or enter into royalty or license agreements, which may not be available on acceptable terms, or at all. If a successful claim of infringement were made against us and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, we may be forced to stop selling current products or abandon new products under development and we could be exposed to legal actions by

30

#### **Table of Contents**

We have initiated, and may need to further initiate, lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would reduce our ability to compete in the market.

We rely on patents to protect a portion of our intellectual property and our competitive position. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to:

assert claims of infringement;
enforce our patents;
protect our trade secrets or know-how; or
determine the enforceability, scope and validity of the proprietary rights of others.

Currently, we have initiated a number of lawsuits against competitors whom we believe to be selling products that infringe our proprietary rights. These current lawsuits and any other lawsuits that we initiate could be expensive, take significant time and divert management s attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us.

Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in our industry are generally uncertain. We may not prevail in any of these suits and the damages or other remedies awarded, if any, may not be commercially valuable. During the course of these suits, there may be public announcements of the results of hearings, motions and other interim proceedings or developments in the litigation. If securities analysts or investors perceive any of these results to be negative, the trading price of the new notes may decline.

Non-competition obligations and other restrictions will limit our ability to take full advantage of our management team, the technology we own or license and our research and development capabilities.

Members of our management team have had significant experience in the diabetes field. In addition, technology we own or license may have potential applications to this field and our research and development capabilities could be applied to this field. However, in conjunction with our split-off from Inverness Medical Technology, Inc., or IMT, we agreed not to compete with IMT and Johnson & Johnson in the field of diabetes through 2011. In addition, our license agreement with IMT prevents us from using any of the licensed technology in the field of diabetes. As a result of these restrictions, we are limited in our ability to pursue opportunities in the field of diabetes at this time.

Our operating results may fluctuate due to various factors and as a result period-to-period comparisons of our results of operations will not necessarily be meaningful.

Factors relating to our business make our future operating results uncertain and may cause them to fluctuate from period to period. Such factors include:

the timing of new product announcements and introductions by us and our competitors;

market acceptance of new or enhanced versions of our products;

the extent to which our current and future products rely on rights belonging to third parties;

changes in manufacturing costs or other expenses;

competitive pricing pressures;

changes in healthcare reimbursement policies and amounts;

public health measures or changes in practices or conduct which may increase or decrease incidents of disease or the need for diagnostic testing;

31

#### **Table of Contents**

regulatory changes;

the gain or loss of significant distribution outlets or customers;

increased research and development expenses;

liabilities and costs associated with litigation;

length of sales cycle and implementation process for new health management customers;

the costs and timing of any future acquisitions;

general economic conditions; or

general stock market conditions or other economic or external factors.

Because our operating results may fluctuate from quarter to quarter, it may be difficult for us or our investors to predict future performance by viewing historical operating results.

#### Period-to-period comparisons of our operating results may not be meaningful due to our acquisitions.

We have engaged in a number of acquisitions in recent years, which makes it difficult to analyze our results and to compare them from period to period. Significant acquisitions since 2007 include our acquisitions of Instant in March 2007, Biosite in June 2007, Cholestech in September 2007, Matria in May 2008, the ACON second territory business in April 2009, and Standard Diagnostics in February 2010. Period-to-period comparisons of our results of operations may not be meaningful due to these acquisitions and are not indications of our future performance. Any future acquisitions will also make our results difficult to compare from period to period in the future.

# The terms of the Series B Preferred Stock may limit our ability to raise additional capital through subsequent issuances of preferred stock.

For so long as any shares of Series B Preferred Stock remain outstanding, we are not permitted, without the affirmative vote or written consent of the holders of at least two-thirds of the Series B Preferred Stock then outstanding, to authorize or designate any class or series of capital stock having rights on liquidation or as to distributions (including dividends) senior to the Series B Preferred Stock. This restriction could limit our ability to plan for or react to market conditions or meet extraordinary capital needs, which could have a material adverse impact on our business.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. You can identify these statements by forward-looking words such believe, as may. could. should. would. intend. will. expect, anticipate. estimate. continue or sin read statements that contain these words carefully because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other forward-looking information. There may be events in the future that we are unable to predict accurately or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. We caution investors that all forward-looking statements involve risks and uncertainties, and actual results may differ materially from those we

discuss in this prospectus. These differences may be the result of various factors, including the factors identified in the section entitled Risk Factors in this prospectus, the factors identified in the sections entitled Risk Factors in our annual report on Form 10-K/A for the year ended December 31, 2009 and our quarterly report on Form 10-Q for the nine months ended September 30, 2010, and other factors identified from time to time in

32

#### **Table of Contents**

our periodic filings with the SEC. Some important factors that could cause our actual results to differ materially from those projected in any such forward-looking statements are as follows:

our inability to predict the effects of the current national and worldwide financial and economic crisis, including disruptions in the capital and credit markets, and potential legislative and regulatory responses to the crisis;

our inability to predict the effects of anticipated United States national healthcare reform legislation and similar initiatives in other countries:

economic factors, including inflation and fluctuations in interest rates and foreign currency exchange rates, and the potential effect of such fluctuations on revenues, expenses and resulting margins;

competitive factors, including technological advances achieved and patents obtained by competitors and general competition;

domestic and foreign healthcare changes resulting in pricing pressures, including the continued consolidation among healthcare providers, trends toward managed care and healthcare cost containment and laws and regulations relating to sales and promotion, reimbursement and pricing generally;

laws and regulations affecting domestic and foreign operations, including those relating to trade, monetary and fiscal policies, taxes, price controls, regulatory approval of new products, licensing and environmental protection;

manufacturing interruptions, delays or capacity constraints or lack of availability of alternative sources for components for our products, including our ability to successfully maintain relationships with suppliers, or to put in place alternative suppliers on terms that are acceptable to us;

difficulties inherent in product development, including the potential inability to successfully continue technological innovation, complete clinical trials, obtain regulatory approvals or clearances in the United States and abroad and the possibility of encountering infringement claims with respect to patent or other intellectual property rights which can preclude or delay commercialization of a product;

significant litigation adverse to us including product liability claims, patent infringement claims and antitrust claims;

product efficacy or safety concerns resulting in product recalls or declining sales;

the impact of business combinations and organizational restructurings consistent with evolving business strategies;

our ability to satisfy the financial covenants and other conditions contained in the agreements governing our indebtedness;

our ability to effectively manage the integration of our acquisitions into our operations;

our ability to obtain required financing on terms that are acceptable to us; and

the issuance of new or revised accounting standards by the American Institute of Certified Public Accountants, the Financial Accounting Standards Board, the Public Company Accounting Oversight Board or the SEC or the impact of any pending unresolved SEC comments.

The foregoing list provides many, but not all, of the factors that could impact our ability to achieve the results described in any forward-looking statement. Readers should not place undue reliance on our forward-looking statements. Before you invest in the new notes, you should be aware that the occurrence of the events described above and elsewhere in this prospectus could seriously harm our business, prospects, operating results and financial condition. We do not undertake any obligation to update any forward-looking statement as a result of future events or developments.

33

#### **Table of Contents**

#### SELECTED CONSOLIDATED FINANCIAL INFORMATION AND OTHER DATA

The following tables provide our selected consolidated financial data as of the dates and for the periods shown. Our selected consolidated statement of operations data for the years ended December 31, 2007, 2008 and 2009 and our selected consolidated balance sheet data as of December 31, 2008 and 2009 are derived from our consolidated financial statements incorporated by reference in this prospectus, which have been audited by BDO USA, LLP (formerly known as BDO Seidman, LLP), our former independent registered public accounting firm, as indicated in their report attached thereto. Our selected consolidated statement of operations data for the years ended December 31, 2005 and 2006 and our selected consolidated balance sheet data as of December 31, 2005, 2006 and 2007 are derived from our consolidated financial statements not incorporated by reference in this prospectus, which have been audited by BDO USA, LLP (formerly known as BDO Seidman, LLP), our former independent registered public accounting firm. Our selected consolidated statement of operations data for the nine months ended September 30, 2009 and 2010 and our selected consolidated balance sheet data as of September 30, 2010 are derived from our unaudited consolidated financial statements incorporated by reference herein, have been prepared on the same basis as our audited consolidated financial statements and, in the opinion of management, include all adjustments (consisting of only normal recurring adjustments) necessary for a fair presentation thereof. Our interim results are not necessarily indicative of our results for the entire year or for any future periods.

The selected consolidated financial data set forth below should be read in conjunction with, and are qualified in their entirety by reference to, our audited and unaudited consolidated financial statements, including the related notes thereto, incorporated by reference herein, or, in the case of our selected consolidated statement of operations data for the years ended December 31, 2005 and 2006 and our selected consolidated balance sheet data as of December 31, 2005, 2006 and 2007, not incorporated by reference herein but included in our annual reports on Form 10-K for such periods and, in each case, the related Management s Discussion and Analysis of Financial Condition and Results of Operations.

On January 15, 2010, we completed the sale of our vitamins and nutritional supplements business. The sale included our entire private label and branded nutritionals businesses and represents the complete divestiture of our entire vitamins and nutritional supplements business segment. The results of the vitamins and nutritional supplements business are included in income (loss) from discontinued operations, net of tax, for all periods presented in the statement of operations data below. The assets and liabilities associated with the vitamins and nutritional supplements business have been reclassified to current classifications as assets held for sale and liabilities related to assets held for sale and, as such, have impacted working capital amounts, which are reflected in the balance sheet data section below, for all balance sheet dates presented.

We have also engaged in a number of acquisitions in recent years, which makes it difficult to analyze our results and to compare them from period to period. Significant acquisitions since 2007 include our acquisitions of Instant in March 2007, Biosite in June 2007, Cholestech in September 2007, Matria in May 2008, the ACON second territory business in April 2009, and Standard Diagnostics in February 2010. Period-to-period comparisons of our results of operations may not be meaningful due to these transactions and are not indications of our future performance. Any future acquisitions or dispositions will also make our results difficult to compare from period to period.

For the Year Ended December 31, Ended September 30, 2005 2006 2007 2008 2009 2010 (Unaudited)

# (In thousands, except ratios)

Statement of Operations Data											
Net product sales Services revenue	\$ 331,046	\$ 470,079	\$ 728,091 16,646	\$ 1,151,265 405,462	\$ 1,365,079 528,487	\$ 972,603 383,279	\$ 1,063,549 497,292				
			10,040	403,402	320,407	363,219	491,292				
Net product sales and services											
revenue	331,046	470,079	744,737	1,556,727	1,893,566	1,355,882	1,560,841				
License and royalty revenue	15,393	17,324	21,979	25,826	29,075	20,588	16,052				
Net revenue	346,439	487,403	766,716	1,582,553	1,922,641	1,376,470	1,576,893				
Cost of net											
product sales Cost of services	192,326	257,785	365,545	543,317	619,503	446,352	500,990				
revenue			5,261	177,098	240,026	172,123	238,991				
34											

# **Table of Contents**

	2005	For the Year Ended December 31, 2006 2007 2008		2009	For the Nine Months Ended September 30, 2009 2010 (Unaudited)			
		(In thousands, except ratios)						
Cost of license and royalty revenue	4,539	5,432	9,149	8,620	8,890	5,352	5,411	
Cost of net revenue	196,865	263,217	379,955	729,035	868,419	623,827	745,392	
Gross profit Operating expenses: Research and	149,574	224,186	386,761	853,518	1,054,222	752,643	831,501	
development Purchase of in-process research	30,992	48,706	69,547	111,828	112,848	80,811	96,187	
and development		4,960	173,825					
Sales and marketing General and	66,300	89,700	163,028	381,939	441,646	316,880	369,016	
administrative Loss (gain) on	56,045	67,938	155,153	295,059	357,033	247,377	284,155	
dispositions, net		3,498			(3,355)	(3,355)		
Operating (loss) income Interest expense and other expenses, net, including amortization of original issue discounts and	(3,763)	9,384	(174,792)	64,692	146,050	110,930	82,143	
write-off of deferred financing costs	(7,536)	(17,595)	(73,563)	(102,939)	(105,802)	(71,074)	(86,240)	
(Loss) income from continuing operations before provision (benefit)								
for income taxes Provision (benefit)	(11,299)	(8,211)	(248,355)	(38,247)	40,248	39,856	(4,097)	
for income taxes	6,971	5,712	(1,049)	(16,644)	15,627	12,901	(964)	
(Loss) income from continuing operations before equity earnings of unconsolidated	(18,270)	(13,923)	(247,306)	(21,603)	24,621	26,955		

entities, net of tax