GEN PROBE INC
Form 10-K
February 24, 2011

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2010

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission file number: 000-49834

Gen-Probe Incorporated
(Exact name of registrant as specified in its charter)

Delaware	**33-0044608**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*
10210 Genetic Center Drive, San Diego, CA	**92121-4362**
(Address of principal executive office)	*(Zip Code)*

Registrant s telephone number, including area code:
(858) 410-8000
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.0001 per share	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes þ No o

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. 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 þ Accelerated filer o Non-accelerated filer o Smaller reporting company o
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No þ

As of June 30, 2010, the last business day of the registrant s most recently completed second fiscal quarter, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was approximately $1.9 billion, based on the closing price of the registrant s common stock on the Nasdaq Global Select Market on that date. Shares of common stock held by each officer and director and by each person who owns 10 percent or more of the outstanding common stock have been excluded because these persons may be considered affiliates. The determination of affiliate status for purposes of this calculation is not necessarily a conclusive determination for other purposes.

As of February 18, 2011, 48,278,460 shares of registrant s common stock, $0.0001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company s definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year are incorporated by reference into Part III of this report.

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PART I

TRADEMARKS AND TRADE NAMES

ACCUPROBE, AMPLIFIED MTD, APTIMA, APTIMA COMBO 2, DTS, ELUCIGENE, GASDIRECT, GEN-PROBE, GTI DIAGNOSTICS, LEADER, LIFECODES, PACE, PANTHER, PROADENO, PRODESSE, PROFAST, PROFLU, PROGASTRO, PROGENSA, TIGRIS and our other logos and trademarks are the property of Gen-Probe Incorporated or its subsidiaries. PROCLEIX and ULTRIO are trademarks of Novartis Vaccines & Diagnostics, Inc., or Novartis. XMAP is a trademark of Luminex Corporation, or Luminex. AVODART is a trademark of GlaxoSmithKline. All other brand names or trademarks appearing in this Annual Report on Form 10-K, or Annual Report, are the property of their respective holders. Use or display by us of other parties trademarks, trade dress or products in this Annual Report does not imply a relationship with, or endorsement or sponsorship of, us by the trademark or trade dress owners.

FORWARD-LOOKING STATEMENTS

This Annual Report and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or if they prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes expressed or implied by the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as believes, expects, hopes, may, will, plans, intends, estimates, could, should, would, continue, seeks or anticipates, or otl (including their use in the negative), or by discussions of future matters, such as the development and commercialization of new products, technology enhancements, regulatory approvals or clearance, possible changes in legislation and other statements that are not historical. These statements include, but are not limited to, statements under the captions Business, Risk Factors, and Management s Discussion and Analysis of Financial Condition and Results of Operations, as well as other sections in this Annual Report. You should be aware that the occurrence of any of the events discussed under the heading Item 1A Risk Factors and elsewhere in this Annual Report could substantially harm our business, results of operations and financial condition. If any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this Annual Report are intended to be applicable to all related forward-looking statements wherever they may appear in this Annual Report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report.

USE OF EXTERNAL ESTIMATES

This Annual Report includes market share and industry data and forecasts that we obtained from industry publications and surveys. Industry publications, surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but there can be no assurance as to the accuracy or completeness of included information. We have not independently verified any of the data from third-party sources nor have we ascertained the underlying economic assumptions relied upon therein. While we are not aware of any misstatements

regarding the industry and market data presented herein, the data involve risks and uncertainties and are subject to change based on various factors.

AVAILABLE INFORMATION

We make available free of charge on or through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange

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Commission, or the SEC. Our Internet address is http://www.gen-probe.com. The information contained in, or that can be accessed through, our website is not part of this Annual Report nor is such information incorporated by reference herein.

Item 1. *Business*

Corporate Overview

Gen-Probe Incorporated (NASDAQ: GPRO) is a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective molecular diagnostic products and services that are used primarily to diagnose human diseases, screen donated human blood, and ensure transplant compatibility. Our molecular diagnostic products are designed to detect diseases more rapidly and/or accurately than older tests, and are among the fastest-growing categories of the *in vitro* diagnostics, or IVD, industry.

We market a broad portfolio of nucleic acid tests, or NATs, to detect infectious microorganisms, including those causing sexually transmitted diseases, or STDs, tuberculosis, strep throat, and other infections. Our leading clinical diagnostics products include our APTIMA family of assays that are used to detect the common STDs chlamydia and gonorrhea.

In 2009 and 2010, we expanded our portfolio of products with acquisitions focused on transplant-related and respiratory diagnostics. Our transplant diagnostics business, which we obtained as part of our acquisition of Tepnel Life Sciences plc, or Tepnel, in April 2009, offers diagnostics to help determine the compatibility between donors and recipients in tissue and organ transplants. Our acquisition of Prodesse, Inc., or Prodesse, in October 2009 added a portfolio of real-time polymerase chain reaction, or real-time PCR, products for detecting influenza and other infectious organisms. In addition, in December 2010, we acquired GTI Diagnostics, a manufacturer of certain of our transplant diagnostic products, in addition to specialty coagulation and transfusion-related blood bank products.

In blood screening, we developed and manufacture the PROCLEIX assays, which are used to detect human immunodeficiency virus (type 1), or HIV-1, the hepatitis C virus, or HCV, the hepatitis B virus, or HBV, and the West Nile virus, or WNV, in donated human blood. These blood screening products are marketed worldwide by Novartis under Novartis trademarks.

Several of our current and future molecular tests can be performed on our TIGRIS instrument, a fully automated, high-throughput NAT system for diagnostics and blood screening. We are building on the success of our TIGRIS instrument system by developing and commercializing our next-generation PANTHER instrument, which is designed to be a versatile, fully automated NAT system for low- to mid-volume laboratories. The PANTHER instrument was CE-marked and launched in Europe in the fourth quarter of 2010.

Our development pipeline includes products to detect:

- human papillomavirus, or HPV, which causes cervical cancer;
- gene-based markers for prostate cancer;
- Trichomonas, a common parasite that causes a highly prevalent STD;
- certain respiratory infections;
- antigens and antibodies that are used to determine transplant and transfusion compatibility; and

specialty coagulation products.

Company History

Gen-Probe was founded in 1983, and was incorporated under the laws of the state of Delaware in 1987. In September 2002, we were spun off from Chugai Pharmaceutical Co., Ltd., our former indirect parent, as a separate, stand-alone company. Our common stock began trading on The Nasdaq Global Select Market on September 16, 2002. Our headquarters facility is located in San Diego and we employ approximately 1,400 people.

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Recent Transactions

Acquisition of Tepnel Life Sciences plc

In April 2009, we acquired Tepnel (now known as Gen-Probe Life Sciences Ltd.), a United Kingdom-based international life sciences products and services company, for approximately $137.1 million (based on the then applicable GBP to USD exchange rate). Our acquisition of Tepnel has provided us with growth opportunities in transplant diagnostics, genetic testing and pharmaceutical services, as well as accelerated our ongoing strategic efforts to strengthen our marketing and sales, distribution and manufacturing capabilities in Europe.

Spin-off of Industrial Testing Assets to Roka Bioscience, Inc.

In September 2009, we spun-off our industrial testing assets to Roka Bioscience, Inc., or Roka, a newly formed private company. In consideration for our contribution of assets in connection with the transaction, we received shares of preferred stock representing 19.9% of Roka s capital stock on a fully diluted basis. As part of the spin-off transaction, our industrial testing collaboration agreements with GE Water (a division of GE Energy, a business unit of General Electric) and Millipore Corporation were transferred to Roka.

Acquisition of Prodesse, Inc.

In October 2009, we acquired Prodesse, a privately held Wisconsin corporation, for approximately $60.0 million, subject to a designated pre-closing operating income adjustment, and up to an aggregate of $25.0 million in potential additional cash payments based on the achievement of certain specified performance measures. As a result of the failure to achieve a specified milestone, the maximum amount of contingent consideration we may be required to pay for our acquisition of Prodesse has been reduced to $15.0 million, of which $10.0 million was paid in July 2010. We do not currently expect to make any further milestone payments related to our acquisition of Prodesse. Our acquisition of Prodesse has provided us with access to the respiratory and gastrointestinal infectious disease markets, which we believe supports our strategic focus on commercializing differentiated molecular tests for infectious diseases.

Sale of BioKits Food Safety Testing Business

In December 2009, we sold our BioKits food safety testing business to Neogen Corporation. This business, which we acquired as part of our acquisition of Tepnel earlier in 2009, includes tests for food allergens, meat and fish speciation, and plant genetics. We believe the divestiture of this business is consistent with our strategic focus on human molecular diagnostic opportunities.

Collaboration with and Investment in Pacific Biosciences of California, Inc.

In June 2010, we entered into a collaboration agreement with Pacific Biosciences of California, Inc., or Pacific Biosciences, regarding the research and development of instruments integrating our sample preparation technologies and Pacific Biosciences single-molecule deoxyribonucleic acid, or DNA, sequencing technologies for use in clinical diagnostics. Subject to customary termination rights, the initial term of the collaboration will end on the earlier of December 15, 2012 or six months after Pacific Biosciences demonstrates the proof of concept of its V2 single-molecule DNA sequencing system. Concurrently with the execution of the collaboration agreement, we also purchased $50.0 million of Pacific Biosciences Series F preferred stock, as a participant in Pacific Biosciences Series F preferred stock round of financing that raised a total of approximately $109.0 million. In October 2010, Pacific Biosciences completed an initial public offering of its common stock. As a result of the initial public offering, our preferred stock was converted into common stock.

Acquisition of GTI Diagnostics

In December 2010, we acquired Genetic Testing Institute, Inc., a privately held Wisconsin corporation doing business as GTI Diagnostics, for approximately $53.0 million on a net-cash basis. Our acquisition of GTI Diagnostics has broadened and strengthened our transplant diagnostics business, and has also provided us access to new products in the specialty coagulation and transfusion-related blood bank markets.

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Strategy

We intend to increase our scale and expand our geographic reach, both by investing in our existing businesses and by acquiring new businesses that are consistent with our strategy. We intend to compete in the women s health, infectious diseases, blood screening and transplant diagnostics markets, and expand into adjacent markets where our core strengths give us a sustainable competitive advantage. We expect that our PANTHER program will be central to our strategy of bringing superior automation to our customers, and along with TIGRIS, will serve as the core of our instrument platform strategy for the coming years.

The focus of our women s health strategy will continue to be our chlamydia and gonorrhea business, where we intend to invest in technologies and products to maintain or expand our market share. We also intend to commercialize our HPV screening assay and related products, with the goal of becoming one of the leaders in this market over time. In addition, we expect to develop and commercialize niche assays that expand and complement our product menus.

We have a portfolio of respiratory infectious disease products as a result of our acquisition of Prodesse in October 2009, and we intend to continue to develop products to serve the infectious disease market. We also intend to pursue internal development programs to establish a leadership position in the virology market.

In blood screening, we partner with Novartis to ensure the safety of the worldwide blood supply. We intend to continue to work with Novartis to maintain the vitality of our blood screening business by investing in areas that promise strong returns on our investment, and by developing our PANTHER instrument platform in the blood screening market.

Our transplant diagnostics business comprises our human leukocyte antigen, or HLA, products and related assays. We intend to continue to invest in our transplant diagnostics business in order to improve our market positioning, broaden our product offering and develop our technological capabilities.

We also intend to continue to expand into adjacent markets within clinical diagnostics, beginning with genetic testing, which includes prostate oncology and companion diagnostics, as well as other markets where we believe we can establish a competitive advantage. We believe that our collaboration with Pacific Biosciences related to genetic sequencing could support our efforts in this area over the longer term.

Competitive Strengths

Assay Development

We believe our core technologies and scientific expertise enable us to develop diagnostic and blood screening assays with superior performance over competing NAT products. We measure performance in terms of sensitivity, specificity, speed of results and ease of use. For example, independent investigators have published several studies demonstrating that our APTIMA Combo 2 assay for chlamydia and gonorrhea is more sensitive than competing molecular tests. In addition, we believe we have enhanced our ability to develop infectious disease assays based on real-time PCR technology through our acquisition of Prodesse.

Instrument Development and Automation

We believe we have the capability to develop instrument platforms that offer superior automation. We have commercialized what we believe to be the world s first fully automated, integrated, high-throughput, NAT instrument system, the TIGRIS instrument. Launched in 2004, the TIGRIS instrument significantly reduces labor costs and contamination risks in high-volume diagnostic testing environments, and enables large blood screening centers to

individually test donors blood. We are building on the success of TIGRIS by developing and commercializing a new automated instrument platform, called the PANTHER system, designed for low- to mid-volume customers, which we believe will be a pillar in our future instrumentation platform strategy. The PANTHER instrument was CE-marked and launched in Europe in the fourth quarter of 2010 and we intend to seek regulatory clearance for the PANTHER system in the United States. We believe that the use of automated instrumentation, such as our TIGRIS and PANTHER instruments, will facilitate growth in both the clinical diagnostics and blood screening portions of the NAT market.

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Innovation

As of December 31, 2010, we had 318 full-time and temporary employees in research and development. We believe that compared to our peers, we invest a higher percentage of our revenue in research and development, with expenses totaling $111.1 million in 2010, $106.0 million in 2009 and $101.1 million in 2008. Based on these investments, we had more than 540 United States and foreign patents covering our products and technologies as of December 31, 2010. We were awarded a 2004 National Medal of Technology, the nation s highest honor for technological innovation, in recognition of our pioneering work in developing NAT testing systems to safeguard the nation s blood supply.

Sales and Service

As of December 31, 2010, our direct sales force consisted of 65 employees and a 62-member technical field support group who target customers in the United States, Canada and certain countries in Europe. We believe these individuals comprise one of the most knowledgeable and effective sales and support organizations in our industry. Our sales representatives have an average of approximately 13 years of overall sales experience. We view our long-standing relationships with laboratory customers and the value-added services that our sales force and technical field specialist group offer, including technical product assistance, customer support and new product training, as central to our success in the United States clinical diagnostics market, and we are looking to duplicate this success as we expand our sales force in Europe. We complement our sales force with leading international distributors and the direct sales organizations of our collaborative partners.

Quality

We are committed to quality in our products, operations and people. Our products, design control and manufacturing processes are regulated by numerous third parties, including the United States Food and Drug Administration, or FDA, foreign governments, independent standards auditors and customers. Our team of 205 full-time and temporary employees in regulatory, clinical and quality has successfully led us through multiple quality and compliance inspections and audits. For example, our blood screening manufacturing facility meets the strict standards set by the FDA s Center for Biologics Evaluation and Research, or CBER, for the production of blood screening products. We believe our expertise in regulatory and quality assurance and our manufacturing facilities enable us to efficiently and effectively design, manufacture and secure approval for new products and technologies that meet the standards set by governing bodies and our customers. We have implemented modern quality systems and concepts throughout our organization. Our regulatory and quality assurance departments supervise our quality systems and are responsible for assuring compliance with all applicable regulations, standards and internal policies. Our senior management team is actively involved in setting quality policies, managing regulatory matters and monitoring external quality performance.

Markets

The NAT market developed in response to a need for more rapid, sensitive and specific diagnostic tests for the detection of infectious microorganisms than were previously available using traditional laboratory methods, such as culture and immunoassays. Culture methods require the growth of a microorganism in a controlled medium and can take several days or longer to yield a definitive diagnostic result. By contrast, nucleic acid probes, which specifically bind to nucleic acid sequences that are known to be unique to the target organisms, can generally deliver an accurate diagnostic result in just hours. The greater sensitivity and increased specificity of NATs relative to immunoassays allows for the detection of the presence of a lower concentration of the target organism and helps clinicians distinguish between harmful and benign microorganisms, even when the organisms are closely related, reducing the potential for false negative and false positive results. For example, the greater sensitivity of amplified NAT allows for

the rapid, direct detection of a target organism like C*hlamydia trachomatis* in urine, even when it is present in low concentrations.

We are focused on NAT market opportunities in women s health, infectious diseases, blood screening and transplant diagnostics. We are also expanding into adjacent areas where we believe our capabilities give us a sustainable competitive advantage, beginning with genetic testing, which includes prostate oncology and

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companion diagnostics. We believe that our collaboration with Pacific Biosciences related to genetic sequencing could support our efforts in this area over the longer term. In addition, as a result of our acquisition of Tepnel, we also offer services for the pharmaceutical, biotechnology and healthcare industries through our research products and services business, which includes nucleic acid purification and analysis services, as well as the sale of monoclonal antibodies.

Women s Health

Chlamydia and Gonorrhea. NAT assays are currently used to detect the microorganisms causing various STDs, including chlamydia and gonorrhea, the two most common bacterial STDs. Chlamydia, the common name for the bacterium C*hlamydia trachomatis*, causes the most prevalent bacterial sexually transmitted infection in the United States, with an estimated 2.8 million new cases in the United States each year according to the Centers for Disease Control and Prevention, or CDC. The clinical consequences of undiagnosed and untreated chlamydia infections include pelvic inflammatory disease, ectopic pregnancy and infertility.

Gonorrhea, the disease caused by the bacterium *Neisseria gonorrhoeae*, is the second most frequently reported bacterial STD in the United States, according to the CDC. The CDC estimates that each year approximately 700,000 people in the United States contract gonorrhea. Untreated gonorrhea is also a major cause of pelvic inflammatory disease, which may lead to infertility or abnormal pregnancies. In addition, recent data suggest that gonorrhea facilitates HIV transmission.

Chlamydia and gonorrhea infections frequently co-exist, complicating the clinical differential diagnosis. Because chlamydia and gonorrhea infections are often asymptomatic, screening programs are important in high-risk populations, such as sexually active men and women between the ages of 15 and 25.

According to internal market research, our products represented approximately 60% of the total chlamydia and gonorrhea tests sold in the United States in 2010.

Human papillomavirus (HPV). HPV is a group of viruses with more than 100 sub-types, 14 of which have been categorized as high risk for the development of cervical cancer. While most women will be infected with HPV at some point in their lives, the majority of these infections are transient and resolve without any clinical symptoms or consequences. However, a small number of HPV infections progress and result in disease ranging from genital warts to cervical cancer. Since most HPV infections do not result in cancer, there is a need for a more specific test to identify women at greater risk of developing that disease.

The most common test used for cervical cancer screening in the United States is the Pap test. Since the mid-1950s, screening with the Pap test has dramatically reduced the number of deaths from cervical cancer. Even so, the American Cancer Society estimates that there will be more than 12,000 new cases of invasive cervical cancer in 2010, and more than 4,000 deaths from the disease.

Despite the success of Pap testing in reducing mortality from cervical cancer in the United States, it suffers from limitations. One such limitation is poor sensitivity of individual Pap smears, which means the test may miss cancers or precancerous changes. As a result, regular and repeated Pap testing is required to effectively detect a high proportion of cervical cancers. Another limitation is that approximately 2 million of the 55 million Pap tests performed annually in the United States have equivocal results, which are known as ASC-US. These women are often subjected to additional invasive tests, including biopsies, most of which prove negative.

In May 2008, we launched our APTIMA HPV assay in Europe. The assay has been CE-marked for use on the TIGRIS system and on our semi-automated Direct Tube Sampling, or DTS, system. The assay is an amplified NAT that is designed to detect 14 sub-types of high-risk HPV that are associated with cervical cancer. More specifically, the assay

is designed to detect certain messenger ribonucleic acids, or mRNAs, that are made in greater amounts when HPV infections progress toward cervical cancer. We believe that targeting these mRNAs may more accurately identify women at higher risk of having, or developing, cervical cancer than competing assays that target HPV DNA. In the fourth quarter of 2010, we submitted a premarket approval application, or PMA, to the FDA for our investigational APTIMA HPV assay on the TIGRIS system.

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Trichomonas vaginalis. Trichomonas is a sexually transmitted parasite that can cause vaginitis, urethritis, premature membrane rupture in pregnancy, and make women more susceptible to infection with HIV-1, the virus that causes acquired immune deficiency syndrome, or AIDS. The CDC estimates that there are 7.4 million cases of Trichomonas infection annually in the United States, making it even more prevalent than chlamydia and gonorrhea, the most common bacterial sexually transmitted diseases. Screening for Trichomonas is limited today due in part to the shortfalls of current testing techniques. Most testing currently is done via culture methods, which are slow and less sensitive than molecular tests, or wet mount, which requires the microscopic examination of a sample shortly after it is collected.

In June 2010, our APTIMA *Trichomonas vaginalis* assay was CE-marked for use on the TIGRIS system, which enables the sale of the CE-marked assay in Europe. In addition, in the third quarter of 2010, we submitted a 510(k) application to the FDA for clearance of our Trichomonas assay on the TIGRIS system in the United States.

Group B Streptococcus. Group B Streptococcus, or GBS, represents a major infectious cause of illness and death in newborns in the United States and can cause cerebral palsy, visual impairment, permanent brain damage and learning disabilities. Our AccuProbe Group B Streptococcus Culture ID Test offers a rapid, non-subjective method for the identification of GBS based on the detection of specific ribosomal ribonucleic acid, or RNA, sequences.

Infectious Diseases

Influenza and Other Respiratory Infections. In October 2009, we added to our existing menu of infectious disease products by acquiring Prodesse, which offers a number of products in the infectious disease market, with current products principally focused on respiratory infections.

Influenza (flu) viruses are a common cause of serious respiratory infections. Flu refers to illnesses caused by a number of different influenza viruses. Flu can cause a range of symptoms from mild to severe, and in some cases the infection can lead to death. Most healthy people recover from the flu without problems, but certain people are at high risk for serious complications. Flu symptoms may include fever, coughing, sore throat, runny or stuffy nose, headaches, body aches, chills and fatigue. In recent years, several strains of flu, including seasonal flu and the novel H1N1 (swine) flu, have circulated in the United States. Like seasonal flu, illness in people with swine flu can vary from mild to severe. Annual outbreaks of the seasonal flu usually occur during the late fall through early spring.

We market and sell ProFlu+, a real-time PCR assay designed to detect influenza A and B and respiratory syncytial virus, or RSV, and ProFAST+, a real-time PCR assay designed to detect and differentiate three types of influenza A: seasonal H1, novel 2009 H1N1, and seasonal H3, under our Prodesse product line. The ProFAST+ assay was cleared for marketing in the United States by the FDA in July 2010. We had previously sold an earlier version of this assay under the name ProFlu-ST pursuant to an Emergency Use Authorization granted by the FDA because of the swine flu pandemic. Our Prodesse product line also includes ProGastro Cd, a real-time PCR assay for the qualitative detection of toxigenic C. difficile, as well as other tests for respiratory infections.

Tuberculosis. Tuberculosis, or TB, the disease caused by the microorganism *Mycobacterium tuberculosis*, remains one of the deadliest diseases in the world. Our amplified Mycobacterium Tuberculosis Direct, or MTD, test has sensitivity similar to a culture test but can detect the TB pathogen within a few hours. In addition, our MTD test is the only approved assay in the United States with a smear negative claim.

Group A Streptococcus. Group A Streptococcus, or GAS, is the cause of strep throat, which if left untreated may cause serious complications, such as rheumatic fever and rheumatic heart disease. Our Group A Streptococcus Direct Test, or GASDirect assay, is a rapid NAT assay for the direct detection of *Streptococcus pyogenes* in one hour from a throat swab.

Virology. NAT assays can be used to detect viral DNA or RNA in a patient sample. These tests can be qualitative, meaning that the tests simply provide a yes-no answer for the presence or absence of the virus, or quantitative, meaning that the test determines the quantity of virus in the patient sample.

Today, most NAT testing in the virology field is done for HIV and HCV. HIV is the virus responsible for AIDS. Individuals with AIDS show progressive deterioration of their immune systems and become increasingly

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susceptible to various diseases, including many that rarely pose a threat to healthy individuals. HCV is a blood-borne pathogen posing one of the greatest health threats in developing countries. According to the World Health Organization, or WHO, approximately 80% of newly infected patients progress to develop chronic infection, which can lead to both cirrhosis and liver cancer. The WHO reports that approximately 170 million people are infected worldwide with HCV. According to the National Cancer Institute, an estimated 4.1 million people in the United States have been infected with HCV, of whom 3.2 million are chronically infected according to the CDC. Most people with chronic HCV infection are asymptomatic.

We have developed and market qualitative NATs for HIV-1 and HCV in the United States. In addition, we sell analyte specific reagents, or ASRs, for quantitative HCV testing in the United States through our collaboration with Siemens Healthcare Diagnostics, Inc., or Siemens. We are currently investigating opportunities to broaden our virology business, and have begun early development work on a quantitative HIV assay that would be designed to run on our PANTHER instrument.

Blood Screening

According to the WHO, each year more than 80 million units of blood are donated worldwide. Before being used for transfusion, blood must be screened to ensure that it does not contain infectious agents such as viruses. The most commonly screened viruses are HIV, HCV, WNV and HBV.

Prior to the introduction of NAT for blood screening, blood screening centers primarily used immunoassays to determine the presence of blood-borne pathogens through the detection of virus-specific antibodies and viral antigens. These tests either directly detect the viral antigens or detect antibodies formed by the body in response to the virus. However, this immune response may take some time following initial infection. Consequently, if the donor has not developed detectable antibodies or detectable amounts of viral antigens as of the time of the donation, recipients of that blood may be unwittingly exposed to serious disease. NAT technology can detect minute amounts of virus soon after infection by amplifying the nucleic acid material of the viruses themselves, rather than requiring the development of detectable levels of antibodies or viral antigens.

We believe that our products are used to screen over 80% of the United States donated blood supply for HIV-1, HCV and WNV.

Transplant Diagnostics

HLA testing, also known as HLA typing or tissue typing, identifies antigens on white blood cells that determine tissue compatibility for organ transplantation (that is, histocompatibility testing). HLA typing, along with blood type grouping, is used to provide evidence of tissue compatibility. The HLA antigens expressed on the surface of the lymphocytes of the recipient are matched against those from various donors. Human leukocyte antigen typing is performed for kidney, bone marrow, liver, pancreas, and heart transplants. The probability that a transplant will be successful increases with the number of identical HLA antigens. Graft rejection occurs when the immune cells (T-lymphocytes) of the recipient recognize specific HLA antigens on the donor s organ as foreign. The T-lymphocytes initiate a cellular immune response that results in graft rejection. Alternatively, T-lymphocytes present in the grafted tissue may recognize the host tissues as foreign and produce a cell-mediated immune response against the recipient. This is called graft versus host disease, or GVHD, and it can lead to life-threatening systemic damage in the recipient. HLA testing is performed to reduce the probability of both rejection and GVHD, and is also used in the ongoing management of transplant recipients.

The HLA testing products offered by Tepnel and GTI Diagnostics enable us to diversify into the transplant typing market. Tepnel sells xMAP multiplex assays in the field of transplant diagnostics under its development and supply

agreement with Luminex. GTI Diagnostics develops and manufactures the HLA antibody detection products which we sell under our LIFECODES brand. GTI Diagnostics also commercializes a number of other HLA-related testing products, including serological typing trays, enzyme immunoassays, and a range of molecular typing products for donor-recipient matching and patient monitoring.

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Genetic Testing

Prostate Oncology. The field of NAT-based cancer diagnostics is an emerging market as new markers that correlate to the presence of cancer continue to be discovered. According to the Prostate Cancer Foundation, prostate cancer is the most common non-skin cancer in the United States, affecting an estimated one in six men. We acquired exclusive worldwide diagnostic rights to the PCA3 gene from DiagnoCure, Inc., or DiagnoCure, in November 2003. In addition, in April 2006, we entered into a license agreement with the University of Michigan for exclusive worldwide rights to develop diagnostic tests for genetic translocations that have been shown in preliminary studies to be highly specific for prostate cancer tissue.

In November 2006, we launched our CE-marked PROGENSA PCA3 assay, a prostate cancer specific molecular diagnostic test, in Europe. Our ASRs for detection of the PCA3 gene are also available in the United States. ASRs comprise a category of individual reagents utilized by clinical laboratories to develop and validate their own diagnostic tests.

In August 2009, we began a clinical trial intended to secure U.S. regulatory approval of our PROGENSA PCA3 assay for use on our semi-automated DTS instrument systems. We submitted a PMA to the FDA for approval of our PROGENSA PCA3 assay in the third quarter of 2010.

Companion Diagnostics. We believe markets will continue to develop for new applications of NAT technology in other clinical fields. We expect that NAT technology will be used in new applications such as genetic predisposition testing and pharmacogenomics, which involves the study of the relationship between nucleic acid sequence variations in an individual s genome and the individual s response to a particular drug. We believe the emergence of pharmacogenomics and individually targeted therapeutics will create opportunities for diagnostic companies to develop tests to detect genetic variations that affect responses to drug therapies.

Genetic testing to identify individuals at risk of certain diseases and pathological syndromes is emerging as an additional market for NAT technology. Through our acquisition of Tepnel, we gained access to genetic tests that are CE-marked in Europe for cystic fibrosis, Down Syndrome, and familial hypercholesterolemia, among other diseases. In addition, in November 2010 we launched our ELUCIGENE KRAS.BRAF assay, which provides valuable information regarding mutation status that can help clinicians determine the most appropriate treatment course for patients with metastatic colorectal cancer.

Key Product Technologies

APTIMA Family of Technologies

Our APTIMA products integrate our patented transcription-mediated amplification, or TMA, technology, target capture technology, and our patented hybridization protection assay, or HPA, and dual kinetic assay, or DKA, technologies, to produce highly refined amplification assays that increase assay performance, reduce laboratory costs and improve laboratory efficiency. Each of these technologies is described in greater detail below.

Target Capture/Nucleic Acid Extraction Technology. Detection of target organisms that are present in small numbers in a large-volume clinical sample requires that target organisms be concentrated to a detectable level. One way to accomplish this is to isolate the particular nucleic acid of interest by binding it to a solid support. This support, with the target bound to it, can then be separated from the original sample. We refer to such techniques as target capture. We have developed target capture techniques to immobilize nucleic acids on magnetic beads by the use of a capture probe that attaches to the bead and to the target nucleic acid. We use a magnetic separation device to concentrate the target by drawing the magnetic beads to the sides of the sample

tube, while the remainder of the sample is washed away and removed. When used in conjunction with our patented amplification methods, target capture techniques concentrate the nucleic acid target(s) and also remove materials in the sample that might otherwise interfere with amplification.

Transcription-Mediated Amplification (TMA) Technology. The goal of amplification technologies is to produce millions of copies of the target nucleic acid sequences that are present in samples in small numbers. These copies can then be detected using DNA probes. Amplification technologies can yield results in only a few hours versus the several days or weeks required for traditional culture methods. Our patented TMA

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technology is designed to overcome problems faced by other target amplification methods. TMA is a transcription-based amplification system that uses two different enzymes to drive the process. The first enzyme is a reverse transcriptase that creates a double-stranded DNA copy from an RNA or DNA template. The second enzyme, an RNA polymerase, makes thousands of copies of the complementary RNA sequence, known as the RNA amplicon, from the double-stranded DNA template. Each RNA amplicon serves as a new target for the reverse transcriptase and the process repeats automatically, resulting in an exponential amplification of the original target that can produce over a billion copies of amplicon in less than 30 minutes.

Hybridization Protection Assay (HPA) and Dual Kinetic Assay (DKA) Technologies. With our patented HPA technology, we have simplified testing, further increased test sensitivity and specificity, and increased convenience. In the HPA process, the acridinium ester, or AE, molecule is protected within the double-stranded helix that is formed when the probe binds to its specific target. Prior to activating the AE molecule, known as lighting off, a chemical is added that destroys the AE molecule on any unhybridized probes, leaving the label on the hybridized probes largely unaffected. When the light off or detection reagent is added to the specimen, only the label attached to the hybridized probe is left to produce a signal indicating that the target organism s DNA or RNA is present. All of these steps occur in a single tube and without any wash steps, which were required as part of conventional probe tests. Our DKA technology uses two types of AE molecules one that flashes and another one that glows. By using DKA, we have created NAT assays that can detect two separate targets simultaneously.

Other Product Technologies

Our recent acquisitions have expanded our portfolio to include products in the respiratory disease and HLA fields, among others, which are based on certain third party technologies, including Roche s real-time PCR technology, and Luminex s xMAP technology, each of which is described below.

Real-Time Polymerase Chain Reaction Technology (real-time PCR). Real-time PCR is a laboratory technique based on PCR, which is used to amplify and simultaneously quantify a targeted nucleic acid (DNA or RNA) molecule. Real-time PCR enables both detection and quantification of one or more specific sequences in a nucleic acid sample. Real-time PCR follows the general principle of PCR; its key feature is that the amplified nucleic acid is detected as the reaction progresses in real time, rather than at the end of the amplification reaction.

Luminex xMAP Technology. Luminex s xMAP technology combines existing biological testing techniques with advanced digital signal processing and proprietary software. With the technology, discrete bioassays are performed on the surface of color-coded microspheres. These microspheres are read in a compact analyzer that utilizes lasers and high-speed digital signal processing to simultaneously identify the bioassay and measure the individual assay results. To perform a bioassay using xMAP technology, a researcher attaches biochemicals, or reagents, to one or more sets of color-coded microspheres, which are then mixed with an extracted test sample. This mixture is injected into an xMAP analyzer, where the microspheres pass single-file in a fluid stream through two laser beams. The first laser excites the internal dyes that are used to identify the color of the microsphere and the test being performed on the surface of the microsphere. The second laser excites a fluorescent dye captured on the surface of the microsphere that is used to quantify the result of the bioassay taking place. Luminex s proprietary optics, digital signal processors and software record the fluorescent signature of each microsphere and compare the results to the known identity of that color-coded microsphere set. The results are analyzed and displayed in real-time with data stored on the computer database for reference, evaluation and analysis.

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Key Products

In the tables below we identify some of the key products we offer in the various markets we currently serve. As described in more detail in the Risk Factors section included in Item 1A of this Annual Report, for products that have not received regulatory clearance in one or more jurisdictions, there can be no assurance that such product(s) will be approved for sale in the applicable jurisdiction(s).

Women s Health

We have established a market-leading position with respect to assays for the detection of chlamydia and gonorrhea, and have obtained several FDA approvals to compete in this market category.

Product Line	Description	Availability
APTIMA Combo 2 assay	Uses APTIMA technology to simultaneously detect chlamydia and gonorrhea.	Marketed globally.
APTIMA CT, APTIMA GC assays	Standalone NATs that use APTIMA technology to detect chlamydia and gonorrhea.	Marketed globally.
PACE family of assays	Non-amplified NATs to detect chlamydia and gonorrhea.	Marketed globally, including by distributors outside the U.S.
APTIMA Trichomonas assay	Uses APTIMA technology to detect trichomonas	Marketed in Europe; 510(k) application filed in the third quarter of 2010 to obtain FDA clearance for sale within the U.S.
APTIMA Trichomonas ASRs	Analyte specific reagents that use APTIMA technology to enable laboratories qualified under the Clinical Laboratory Improvement Amendments, or CLIA, to detect Trichomonas.	ASRs available in the U.S.
APTIMA HPV assay	Uses APTIMA technology to detect 14 sub-types of high-risk HPV associated with cervical cancer.	Marketed in Europe; PMA filed in the fourth quarter of 2010 to obtain FDA regulatory approval for sale within the U.S.
AccuProbe Group B Streptococcus (GBS) assay	Non-amplified NAT to detect GBS from culture.	Marketed globally, including by distributors outside the U.S.

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Infectious Diseases

Our acquisition of Prodesse in October 2009 added assays for certain respiratory and gastrointestinal diseases to our menu of products in this field, which now includes the products described in the table below.

Product Line	Description	Availability
ProFlu+	30,360	
Due to broker and benefit claims payables	17,517	549
Total liabilities	45,379	30,909
Net assets available for benefits	$ 185,346,634	$ 181,537,633

See accompanying notes to financial statements.

Precision Strip, Inc.

Retirement and Savings Plan

Statement of Changes in Net Assets Available for Benefits

Year ended December 31,	2015
Additions	
Income:	
Interest and dividends	$ 10,572,626
Interest from notes receivable from participants	249,441
Total income	10,822,067
Contributions:	
Employer, net of forfeitures	6,743,439
Participant	3,979,377
Rollover	32,832
Total contributions, net	10,755,648
Total additions	21,577,715
Deductions	
Net depreciation in fair value of investments	10,204,411
Benefits paid to participants and beneficiaries	7,536,587
Administrative expenses	27,716
Total deductions	17,768,714
Net increase	3,809,001
Net assets available for benefits, beginning of year	181,537,633
Net assets available for benefits, end of year	$ 185,346,634

See accompanying notes to financial statements.

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Precision Strip, Inc.

Retirement and Savings Plan

Notes to Financial Statements

1.Description of the Plan

The following brief description of the Precision Strip, Inc. Retirement and Savings Plan (the "Plan") provides only general information. Participants should refer to the Summary Plan Description for a more complete description of the Plan's provisions.

General

The Plan is a defined contribution plan providing retirement benefits covering all employees who meet certain eligibility requirements of Precision Strip, Inc. (the "Company"), a wholly-owned subsidiary of Reliance Steel & Aluminum Co., and Precision Strip Transport, Inc., a wholly-owned subsidiary of Precision Strip, Inc. The Plan is subject to the provisions of the Employee Retirement Income Security Act of 1974 ("ERISA") and subsequent amendments. The Plan is administered by the Precision Strip, Inc. Retirement and Savings Plan Administrative Committee ("Plan Administrator"). Fidelity Management Trust Company ("Fidelity") is the trustee and recordkeeper of the Plan.

Participation

Each employee is eligible to participate on the first day of each plan calendar quarter after the completion of three months of service.

An eligible employee who has satisfied the Plan's waiting period and is first hired is automatically enrolled into the Plan with a 2% deferral of eligible compensation. Unless elected otherwise, their automatic enrollment contribution will increase annually by 2%, to a maximum of 8%. An eligible employee may decline to be automatically enrolled into the Plan and they can also elect a different deferral percentage.

Contributions

Participants may make up to 50% salary deferrals of eligible compensation to the Plan, subject to federal limits. The Plan also allows the Company to make employer profit sharing contributions, which are discretionary. Eligible participants who complete 1,000 hours of service are eligible to receive the employer contribution. Participants may also contribute distributions from other qualified defined benefit or defined contribution plans, and from individual retirement accounts.

Participant Accounts

Each participant's account is credited with the participant's contributions, employer contributions and allocation of investment earnings. The benefit to which a participant is entitled is the benefit that can be provided from the participant's account. Participants may direct the investment of their account balances into various investment funds offered by the Plan.

Vesting

Participants are immediately vested in all employee contributions and eligible rollovers plus actual earnings thereon. Employer profit sharing contributions and any earnings thereon are vested in accordance with the following schedule:

Precision Strip, Inc.

Retirement and Savings Plan

Notes to Financial Statements

Years of Service	Percentage
Less than 2	0%
2	20%
3	40%
4	60%
5	80%
6 or more	100%

Payment of Benefits

On termination of service, or upon death, disability, or retirement, a participant can receive a lump sum amount equal to the vested value of his or her account. A monthly installment payment option is also available. Other withdrawals from participants' account balances may be made under certain circumstances, as defined in the Plan document.

Forfeitures

Forfeitures from nonvested participant accounts are used to reduce future Company contributions. During the year ended December 31, 2015, forfeitures of $108,422 were used to reduce the Company's contributions. Forfeited nonvested accounts totaled $627 and $879 at December 31, 2015 and 2014, respectively.

Notes Receivable from Participants

Participants may borrow from their accounts up to the lesser of $50,000 or 50% of their vested account balance. Loans are secured by the respective participant's vested account balance and are subject to interest charges. Interest rates applicable to new notes are determined by the Plan Administrator on the first day of each calendar quarter based on prevailing market rates. Loans are repaid ratably through periodic payroll deductions over a term not exceeding five years for general purpose loans and up to ten years for the purchase of a primary residence. Interest rates on notes receivable from participants as of December 31, 2015 ranged from 4.25% to 8.25% and mature through December

2025. Interest earned is recorded on an accrual basis as interest income from notes receivable from participants in the Statement of Changes in Net Assets Available for Benefits.

Administrative Expenses

Non-investment costs and administrative expenses of the Plan are paid by the Company, which is a party-in-interest. These expenses, which are not reflected in the accompanying financial statements, constitute exempt party-in-interest transactions under ERISA. Loan establishment, loan maintenance and short-term trading fees are paid by the Plan's participants and all other investment expenses are offset against the related investment income. Fees paid by the Plan participants to the trustee and recordkeeper for administrative expenses amounted to $27,716 for the year ended December 31, 2015.

2.Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements of the Plan are prepared under the accrual method of accounting in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

As described in the Plan Accounting—Defined Contribution Pension Plans topic of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("Codification"), contract value is the relevant measure for investment contracts held by a defined-contribution plan that meet the fully benefit-responsive investment contract criteria. Contract value is the amount participants would receive if they were to initiate permitted transactions under the terms of the Plan.

Precision Strip, Inc.

Retirement and Savings Plan

Notes to Financial Statements

The Plan invests in the Fidelity Managed Income Portfolio which is a common collective trust. It invests in fully benefit-responsive investment contracts issued by insurance companies and other financial institutions, and in fixed income securities (see Investment Valuation and Income Recognition).

Investment Valuation and Income Recognition

The Plan's investments in registered investment companies (mutual funds) and in common stock are stated at fair value based on the quoted market price of the funds or common stock. The investments in registered investment companies represent the net asset value of the shares held by the Plan at year end. The common collective trust is stated at net asset value as determined by the trustee at the end of the Plan year except when holding fully benefit-responsive investment contracts as described below. Purchases and sales of securities are recorded on a trade-date basis. Interest income is recorded on the accrual basis. Dividends are recorded on the ex-dividend date.

The Plan invests in the Fidelity Managed Income Portfolio, a stable value fund held within a common collective trust, which has entered into fully benefit-responsive investment contracts to provide preservation of principal, maintain a stable interest rate, and provide liquidity at contract value for participant withdrawals and transfers. The stable value fund has an investment objective to maintain a constant net asset value while generating a slightly higher yield than the money market fund. Generally, there are no restrictions on a participant's ability to redeem their investment in the common collective trust at the investment's net asset value (NAV). However, withdrawals prompted by certain events (e.g., termination of the managed income portfolio, changes in laws or regulations) may restrict a participant's ability to redeem the investment at its NAV.

Net Appreciation (Depreciation) in Fair Value of Investments

Realized and unrealized appreciation (depreciation) in the fair value of investments is based on the difference between the fair value of the assets at the beginning of the year, or at the time of purchase for assets purchased during the year, and the related fair value on the day investments are sold with respect to realized appreciation (depreciation), or on the last day of the year for unrealized appreciation (depreciation).

Realized and unrealized appreciation (depreciation) is recorded in the accompanying Statement of Changes in Net Assets Available for Benefits as net depreciation in fair value of investments.

Risks and Uncertainties

The Plan provides various funds that hold investment securities. Investment securities are exposed to various risks such as interest rate, market volatility, and credit risks. Due to the level of risk associated with certain investment securities and the level of uncertainty related to changes in the value of investment securities, it is at least reasonably possible that changes in risk in the near term would materially affect participants' account balances and the amounts reported in the financial statements.

The Plan provides investment options that hold securities of foreign companies, which may involve special risks and considerations not typically associated with investing in U.S. companies. These risks include devaluation of currencies, less reliable information about issuers, different securities transaction clearance and settlement practices, and possible adverse political and economic developments. Moreover, securities of many foreign companies and their markets may be less liquid and their prices more volatile than securities of comparable U.S. companies.

Use of Estimates

The preparation of the financial statements, in conformity with U.S. GAAP, requires management to make estimates and assumptions that affect the financial statements and accompanying notes. Actual results could materially differ from those estimates.

Precision Strip, Inc.

Retirement and Savings Plan

Notes to Financial Statements

Payment of Benefits

Benefits paid to participants are recorded when paid.

Recently Issued Accounting Pronouncements

In July 2015, the FASB issued accounting guidance to reduce complexity in employee benefit plan accounting as part of its simplification initiative. This new guidance requires fully benefit-responsive investment contracts to be measured, presented, and disclosed only at contract value. The guidance also eliminated certain investment disclosures. The Plan adopted these changes for the 2015 Plan year and the presentation of the Net Assets Available for Benefits as of December 31, 2014 has been retrospectively adjusted.

In May 2015, the FASB issued accounting guidance that will remove certain disclosures and the requirement to categorize within the fair value hierarchy investments for which fair value is measured using the net asset value per share practical expedient. The guidance should be applied retrospectively to all periods presented and is effective for Plan years beginning after December 15, 2015, with early adoption permitted. Adoption of this new accounting guidance is not expected to have a material impact on the Plan’s financial statements.

3.Investments

Participants may invest in certain investments offered by Fidelity, the trustee and recordkeeper of the Plan, including a unitized common stock fund containing common stock of Reliance Steel & Aluminum Co. and interest bearing cash. At December 31, 2015 and 2014, the Plan held 322,429 and 328,659 unitized shares of Reliance Steel & Aluminum Co. stock fund with fair values of $5,105,695 and $5,345,114, respectively. As of December 31, 2015 and 2014, the Reliance Steel & Aluminum Co. stock fund consisted of 84,606 and 83,676 shares, respectively, of Reliance Steel & Aluminum Co. common shares valued at $4,899,533 and $5,126,828, respectively. At December 31, 2015 and 2014, the fund contained interest-bearing cash of $223,639 and $218,823, respectively, and other receivables of $40 and $12, respectively. The fund also contained $17,517 due to broker for securities purchased as of December 31, 2015 and a benefit claim payable of $549 at December 31, 2014.

For risks and uncertainties regarding investment in Reliance Steel & Aluminum Co. common stock, participants should refer to the Reliance Steel & Aluminum Co.'s Annual Report on Form 10-K for the year ended December 31, 2015 and the Quarterly Report on Form 10-Q for the quarter ended March 31, 2016.

4.Fair Value Measurements

The Codification establishes a framework for measuring fair value. That framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and lowest priority to unobservable inputs (level 3 measurements). The three levels of the fair value hierarchy are described as follows:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities. An active market for the asset or liability is a market in which the transaction for the asset or liability occurs with sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2: Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities in markets that are active; quoted market prices in markets that are not active; or model-derived valuations or other inputs that are observable or can be corroborated by observable market data for substantially the full terms of the assets or liabilities.

Precision Strip, Inc.

Retirement and Savings Plan

Notes to Financial Statements

Level 3: Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The following table sets forth by level, within the fair value hierarchy, the Plan's investment assets measured at fair value as of December 31, 2015:

	Level 1	Level 2	Level 3	Total
Interest-bearing cash	$ 223,639	$ -	$ -	$ 223,639
Mutual funds	161,213,042	-	-	161,213,042
Money market fund	2,121,161	-	-	2,121,161
Reliance Steel & Aluminum Co. common stock	4,899,533	-	-	4,899,533
Total investments at fair value	$ 168,457,375	$ -	$ -	$ 168,457,375

The following table sets forth by level, within the fair value hierarchy, the Plan's investment assets measured at fair value as of December 31, 2014:

	Level 1	Level 2	Level 3	Total
Interest-bearing cash	$ 218,823	$ -	$ -	$ 218,823
Mutual funds	157,860,404	-	-	157,860,404
Money market fund	1,595,265	-	-	1,595,265
Reliance Steel & Aluminum Co. common stock	5,126,828	-	-	5,126,828
Total investments at fair value	$ 164,801,320	$ -	$ -	$ 164,801,320

The Plan's investments that are measured at fair value on a recurring basis, such as the money market fund, mutual funds, and equity securities are generally classified within Level 1 of the fair value hierarchy. The fair values of these

investments are based on quoted market prices in active markets.

5.Related Party Transactions

Certain Plan investments are shares of mutual funds, shares of a common collective trust, shares of a unitized common stock fund and a money market fund managed by Fidelity, the trustee and recordkeeper as defined by the Plan. The Plan also engages in the purchase and sale of Reliance Steel & Aluminum Co. common stock. These transactions qualify as exempt party-in-interest transactions. Additionally, notes receivable from participants also qualify as exempt party-in-interest transactions.

6.Income Tax Status

The Plan’s Trustee received an advisory letter from the Internal Revenue Service (IRS) dated March 31, 2008 confirming the tax qualification status of the Plan document prototype. Although the Plan has been amended since the date of this letter, the Plan Administrator believes the Plan is being operated in compliance with the applicable requirements of the Code and therefore is tax qualified.

The Plan Administrator has analyzed the tax positions taken by the Plan, and has concluded that as of December 31, 2015, there are no uncertain positions taken or expected to be taken that would require provision for income taxes in the accompanying financial statements.

Precision Strip, Inc.

Retirement and Savings Plan

Notes to Financial Statements

7.Plan Termination

Although it has not expressed any intent to do so, the Company has the right under the Plan to discontinue its contributions at any time and to terminate the Plan subject to the provisions of ERISA. In the event of Plan termination, participants will become 100% vested in their accounts.

8.Excess Contributions Payable

Excess contributions payable represents amounts owed to participants who made excess contributions based on the compliance testing performed by the Plan's record keeper. The excess contributions payable balances were returned by the Plan to the participants prior to IRS deadlines.

9.Nonexempt Transactions

As reported on the Form 5500, Schedule H, Line 4a – Schedule of Delinquent Participant Contributions, certain participant contributions and loan repayments were not remitted to the Plan within the time frame specified by the Department of Labor's Regulation 29 CFR 2510.3-102, thus constituting nonexempt transactions between the Plan and the Company during the 2015 Plan year. Late remittances amounted to $100,137 for the 2015 Plan year. The Company is currently in process of making the appropriate filings in accordance with the IRS' Employee Plans Compliance Resolution System and plans to remit lost earnings to the Plan in 2016.

10.Reconciliation of Financial Statements to Form 5500

The following is a reconciliation of net assets available for benefits as reported on the Form 5500 with that reported in the accompanying financial statements:

December 31,	2015	2014
Net assets available for benefits as reported on the Form 5500	$ 185,422,599	$ 181,701,238
Adjustment from fair value to contract value for fully benefit-responsive investment contracts held by a common collective trust	(75,965)	(163,605)
Net assets available for benefits as reported on the accompanying financial statements	$ 185,346,634	$ 181,537,633

The following is a reconciliation of the changes in net assets available for benefits as reported on the Form 5500 with that reported in the accompanying financial statements:

Year ended December 31,	2015
Net increase in net assets available for benefits as reported on the Form 5500	$ 3,721,361
Investments:	
Adjustment from fair value to contract value for fully benefit-responsive investment contracts held by a common collective trust:	
Beginning of year	163,605
End of year	(75,965)
Net increase in net assets available for Plan benefits as reported on the accompanying financial statements	$ 3,809,001

Supplemental Schedules

Precision Strip, Inc.

Retirement and Savings Plan

Schedule H, Line 4a – Schedule of Delinquent Participant Contributions

Employer Identification Number: 34-1207681

Plan Number: 001

Form Number: 5500

Year Ended December 31, 2015	Total that Constitute Nonexempt Prohibited Transactions			
Participant Contributions Transferred Late to Plan	Contributions Not Corrected	Contributions Corrected Outside VFCP	Contributions Pending Correction in VFCP	Total Fully Corrected Under VFCP and PTE 2002-51
Check Here if Late Participant Loan Repayments are included:				
$100,137	$100,137			

Precision Strip, Inc.

Retirement and Savings Plan

Schedule H, Line 4i – Schedule of Assets (Held at End of Year)

Employer Identification Number: 34-1207681

Plan Number: 001

Form Number: 5500

December 31, 2015

	(a)	(b) Identity of Issue, Borrower, Lessor or Similar Party	(c) Description of Investment, including Maturity Date, Rate of Interest, Collateral, Par or Maturity Value	(d) Cost	(e) Current Value
		Mutual Funds:			
*		Fidelity Investments	Fidelity Dividend Growth Fund: Class K	a	$ 21,638,391
*		Fidelity Investments	Spartan 500 Index Fund: Institutional Class	a	20,379,769
		Neuberger Berman	Neuberger Berman Genesis Fund: Institutional Class	a	16,651,467
*		Fidelity Investments	Fidelity Diversified International Fund: Class K	a	9,825,489
*		Fidelity Investments	Fidelity Freedom K 2035 Fund	a	9,495,549
		PIMCO	PIMCO Total Return: Institutional Class	a	8,640,091
*		Fidelity Investments	Fidelity Freedom K 2030 Fund	a	8,539,023
*		Fidelity Investments	Fidelity Freedom K 2040 Fund	a	6,280,121
		American Funds	American Funds The Growth Fund of America R6	a	5,450,816
*		Fidelity Investments	Fidelity Freedom K 2025 Fund	a	5,195,912
*		Fidelity Investments	Fidelity Freedom K 2020 Fund	a	5,162,748
*		Fidelity Investments	Fidelity Puritan Fund: Class K	a	5,125,763
*		Fidelity Investments	Fidelity Freedom K 2045 Fund	a	5,001,194
*		Fidelity Investments	Fidelity Contra Fund: Class K	a	4,601,981
*		Fidelity Investments	Fidelity Freedom K 2050 Fund	a	3,851,206
		American Beacon	American Beacon Large Cap Value Fund: Institutional Class	a	3,210,931
		Janus Funds	Janus Twenty Fund	a	2,785,187
		The Royce Funds	Royce Opportunity Fund: Institutional Class	a	2,038,258
*		Fidelity Investments	Fidelity Value Fund: Class K	a	1,923,803

*	Fidelity Investments	Spartan Total Market Index Fund: Advantage Class	a	1,865,097
*	Fidelity Investments	Fidelity Low-priced Stock Fund: Class K	a	1,834,367
*	Fidelity Investments	Fidelity Freedom K 2055 Fund	a	1,812,433
*	Fidelity Investments	Fidelity Fund: Class K	a	1,544,156
	The Harford Mutual Funds	Hartford Small Company HLS Fund: Class IA	a	1,480,186
*	Fidelity Investments	Fidelity Equity Income Fund: Class K	a	1,407,386
	Morgan Stanley	Morgan Stanley Institutional Mid Cap Growth I	a	1,069,794
*	Fidelity Investments	Fidelity Freedom K Income Fund	a	981,130
*	Fidelity Investments	Fidelity Freedom K 2015 Fund	a	979,754
*	Fidelity Investments	Spartan Intermediate Treasury Bond Index Fund	a	704,138
*	Fidelity Investments	Fidelity Mid Cap Stock Fund: Class K	a	576,636
*	Fidelity Investments	Fidelity Intermediate Bond	a	544,048
*	Fidelity Investments	Spartan Global ex U.S. Index Fund	a	227,808
*	Fidelity Investments	Fidelity Freedom K 2010 Fund	a	203,645
*	Fidelity Investments	Fidelity Freedom K 2060 Fund	a	169,709
*	Fidelity Investments	Fidelity Freedom K 2005 Fund	a	15,056
		Total mutual funds		$ 161,213,042

Precision Strip, Inc.

Retirement and Savings Plan

Schedule H, Line 4i – Schedule of Assets (Held at End of Year)

Employer Identification Number: 34-1207681

Plan Number: 001

Form Number: 5500

December 31, 2015

	(a)	(b) Identity of Issue, Borrower, Lessor or Similar Party	(c) Description of Investment, including Maturity Date, Rate of Interest, Collateral, Par or Maturity Value	(d) Cost	(e) Current Value
		Common Collective Trust:			
*		Fidelity Investments	Fidelity Managed Income Portfolio	a	$ 11,199,660
		Money market fund:			
*		Fidelity Investments	Fidelity Retirement Money Market Portfolio Fund	a	2,121,161
		Common Stock:			
*		Reliance Steel & Aluminum Co.	Common Stock	a	4,899,533
		Interest-bearing cash:			
*		Fidelity Investments	Cash	a	223,639
		Notes receivable from participants:			
*		Notes receivable from participants	Notes receivable from participants with interest rates ranging from 4.25% to 8.25%, collateralized by participants' account balance and maturing through December 2025	-	5,810,903
				Total	$ 185,467,938

* - A party in interest as defined by ERISA.

a - The cost of participant-directed investments is not required to be disclosed.

Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, the members of the Precision Strip, Inc. Retirement and Savings Plan Committee have duly caused this annual report to be signed on its behalf by the undersigned hereunto duly authorized.

PRECISION STRIP, INC.

RETIREMENT AND SAVINGS PLAN

Dated: August 16, 2016 By:/s/ Karla R. Lewis
Karla R. Lewis
Member of the Precision Strip, Inc.
Committee

Exhibit Index

Exhibit No.	Description
23.1	Consent of Independent Registered Public Accounting Firm—BDO USA, LLP