BIO-TECHNE Corp
Form 10-K
August 27, 2018

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended June 30, 2018, or

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 0-17272

BIO-TECHNE CORPORATION

(Exact name of registrant as specified in its charter)

Minnesota	**41-1427402**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
614 McKinley Place N.E. Minneapolis, MN 55413	**(612) 379-8854**

(Address of principal executive offices) (Zip Code) (Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.01 par value	The NASDAQ Stock Market LLC

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 No

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 No

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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, 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 No

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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 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.

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of December 31, 2017 the aggregate market value of the Common Stock held by non-affiliates of the Registrant was $3.4 billion based upon the closing sale price as reported on The Nasdaq Stock Market ($129.55 per share). Shares of Common Stock held by each officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded.

As of August 23, 2018, 37,731,348 shares of the Company's Common Stock ($0.01 par value) were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's Proxy Statement for its 2018 Annual Meeting of Shareholders are incorporated by reference into Part III.

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PART I

ITEM 1. BUSINESS

OVERVIEW

Bio-Techne and its subsidiaries, collectively doing business as Bio-Techne Corporation (Bio-Techne, we, our, us or the Company) develop, manufacture and sell biotechnology reagents, instruments and services for the research and clinical diagnostic markets worldwide. With our deep product portfolio and application expertise, we strive to provide the life sciences community with innovative, high-quality scientific tools to better understand biological processes and drive discovery of diagnostic and therapeutic products.

During our fiscal year 2018, we operated with three reporting segments – our Biotechnology, Protein Platforms and Diagnostics Divisions. Our Biotechnology Division is a leader in providing high quality consumables and services used for conducting laboratory experiments by both industry and academic scientists within the biotechnology and biomedical life sciences fields, all under the primary brands of R&D Systems, Novus Biologicals, Tocris Bioscience, Atlanta Biologicals, Trevigen, and Advanced Cell Diagnostics. Our Protein Platforms Division focuses on developing and supplying instrumentation and related consumables designed to simplify protein analysis processes along with single cell protein analysis, all under the ProteinSimple brand. Through our Diagnostics Division, we serve the clinical markets with regulated products such as controls, calibrators, reagents and immunoassays intended for diagnostic uses.

We are a Minnesota corporation with our global headquarters in Minneapolis, Minnesota. We originally were founded over forty years ago, in 1976, as Research and Diagnostic Systems, Inc. We became a publicly traded company in 1985 through a merger with Techne Corporation, now Bio-Techne Corporation. Our common stock is listed on the NASDAQ under the symbol “TECH.” We operate globally, with offices in multiple locations in the United States, Europe, and Asia. Today, our product line extends to over 300,000 manufactured products in state of the art facilities to accommodate many of our manufacturing needs.

Our historical focus was on providing high quality proteins, antibodies and immunoassays to the life science research market and hematology controls to the diagnostics market. Beginning in 2012, and accelerating over the last three years, we implemented a strategy to accelerate growth in part by acquiring businesses and product portfolios that leveraged and diversified our existing product lines, filled portfolio gaps with differentiated high growth businesses, and expanded our geographic scope. From 2012 through August 27, 2018 we have acquired 15 companies, eight of which expanded our Biotechnology segment both geographically and through product diversification, three that

formed our Protein Platforms segment, and four of which expanded the reach of our Diagnostics segment.

Recognizing the importance of an integrated, global approach to meeting our mission and accomplishing our strategies, we have over the past several years unified our brands and recent acquisitions under a single global brand, Bio-Techne.

We are committed to providing the life sciences community with innovative, high-quality scientific tools that allow our customers to make extraordinary discoveries. Our mission is to build “epic tools for epic science.” We intend to build on Bio-Techne’s past accomplishments, high product quality reputation and sound financial position by executing strategies that position us to serve as the standard for biological content in the research market, and to leverage that leadership position to enter the diagnostics and other adjacent markets. Our strategies include:

Continued innovation in core products. Through collaborations with key opinion leaders, participation in scientific discussions and societies, and leveraging our internal talent we expect to be able to convert our continued significant investment in our research and development activities to be first-to-market with quality products that are at the leading edge of life science researchers’ needs.

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Market and geographic expansion. We will continue to expand our sales staff and distribution channels globally in order to increase our global presence and make it easier for customers to transact with us. We will also leverage our existing portfolio to expand our product offerings into novel research fields and further into diagnostics and therapeutics markets.

Operational excellence. In recognition of the increased size and scale of the organization, we continue to redesign our development and operational processes to effectively and efficiently support our expanding businesses.

Talent recruitment and retention. We strive to recruit, train and retain the most talented staff to implement all of our strategies effectively.

Targeted acquisitions and investments. We will continue to leverage our strong balance sheet to gain access to new technologies and products that improve our competitiveness in the current market, meet customers' expanding work flow needs and allow us to enter adjacent markets.

OUR PRODUCTS AND MARKETS

In fiscal 2018, net sales from Bio-Techne's Biotechnology, Protein Platforms and Diagnostics segments represented 66%, 17%, and 17% of consolidated net sales, respectively. Financial information relating to Bio-Techne's segments is incorporated herein by reference to Note 11 to the Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K.

Biotechnology Segment

Biotechnology Segment Products

Through our Biotechnology segment, we are one of the world's leading suppliers of specialized proteins, such as cytokines and growth factors, immunoassays, antibodies and related reagents, to the biotechnology research community. We also sell *in situ* hybridization, media and other cell culture products and reagents. Our combined chemical and biological reagents portfolio provides high quality tools which customers can use in solving the complexity of important biological pathways and glean knowledge that may lead to a more complete understanding of biological processes, and, ultimately, to the development of novel strategies to address different pathologies.

Additionally, a number of our products have the potential to serve as predictive biomarkers and therapeutic targets for a variety of human diseases and conditions including cancer, autoimmunity, diabetes, hypertension, obesity, inflammation, neurological disorders, and kidney failure. Immunoassays can also be useful in clinical diagnostics. In fact, we have received Food and Drug Administration (FDA) marketing clearance for a few of our immunoassays for use as *in vitro* diagnostic devices. In addition to being useful research tools, our RNA *in situ* hybridization assays have diagnostics applications as well, and several are currently being cleared with the FDA in partnership with diagnostics instrument manufacturers and pharmaceutical companies.

Biotechnology Segment Customers and Distribution Methods

We sell our Biotechnology products directly to customers who are primarily located in North America, Europe and China. We have a sales and marketing partnership agreement with Fisher Scientific in order to bolster our market presence in North America and leverage the transactional efficiencies offered by the large Fisher organization. We also sell through third party distributors in China, Japan, certain eastern European countries and the rest of the world. Our sales are widely distributed, and no single end-user customer accounted for more than 10% of Biotechnology's net sales during fiscal 2018, 2017 or 2016.

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Biotechnology Segment Competitors

A number of companies supply the worldwide market for protein-related and chemically-based research and diagnostic reagents, including GE Healthcare Life Sciences, BD Biosciences, Merck KGaA/EMD Chemicals, Inc., PeproTech, Inc., Abcam plc., and Thermo Fisher Scientific, Inc. Market success is primarily dependent upon product quality, selection, price and reputation. We believe we are one of the leading world-wide suppliers of cytokine and growth factors in the research market. We further believe that the expansion of our product offering, the recognized quality of our products, and the continued demand for protein-related and chemically-based research reagents will allow us to remain competitive in the growing biotechnology research and diagnostic markets.

Biotechnology Manufacturing

We are not dependent on key or sole source suppliers for most of our products in the Biotechnology segment. We develop and manufacture the majority of our proteins using recombinant DNA technology, thus significantly reducing our reliance on outside resources. Our antibodies are produced using a variety of technologies including traditional animal immunization and hybridoma technology as well as recombinant antibody techniques. Our *in situ* hybridization and chemical-based small molecule products are synthesized from widely available products. We typically have several outside sources for all critical raw materials necessary for the manufacture of our products.

The majority of our Biotechnology products are shipped within one day of receipt of the customers' orders. Consequently, we had no significant backlog of orders for our Biotechnology segment products as of the date of this Annual Report on Form 10-K or as of a comparable date for fiscal 2017.

Protein Platforms Segment

Proteins are important for understanding disease because they are the functional units that carry out specific tasks in every cell. Altered levels of certain proteins can prevent the cell from performing its intended function, produce the energy it requires, maintain its morphology or survive within the tissue. However, protein analysis is complex given the varied and unique three-dimensional structure of the many proteins of interest. Our Protein Platforms segment develops, manufactures and sells tools to simplify protein analysis while at the same time achieving more quantitative and reproducible results.

Protein Platforms Segment Products

Our Protein Platforms business has an array of platforms useful in various areas of protein analysis.

Developers of biologics-based drugs are required by regulatory agencies, such as FDA, to develop robust processes to ensure that the specific biologic of interest can be identified and characterized accurately and then consistently and reliably produced. Our Biologics tools help researchers interrogate protein purity and identify contaminants during the development and production of biologics by measuring some elements of protein identity, purity and heterogeneity.

The Western blot, or Western, is one of the most widely-used assays for protein analysis and identification today, and is used by molecular biologists, biochemists and clinicians to determine if a specific protein is present in a sample. Our Simple Western platform is a fully-automated Western blot analytical technique that can identify and quantify a protein of interest in a more sensitive, automated and less time-intensive manner.

A common assay used in research and clinical diagnostics is the ELISA, or enzyme-linked immunosorbent assay. The SimplePlex platform is a transformative immunoassay technology which integrates an innovatively designed microfluidic cartridge with a state-of-the-art analyzer to deliver a bench-top immunoassay system that is more sensitive than a manual multi-well place based ELISA with none of the traditional challenges of assay design or repeatability.

The Single Cell Western platform and related reagents perform western blot assays on individual cells versus an entire cell population. With this tool, customers can elucidate the properties of individual cells to better understand cell behavior that can shape the overall cell population response in a disease or normal state.

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Protein Platforms Segment Customers and Distribution Methods

Our customers for this segment include researchers in academia as well as by investigators in industry, such as pharmaceutical and biotech companies. Our biologics line of products is used primarily by production and quality control departments at biotech and pharmaceutical companies. We sell our Protein Platforms products directly to customers who are primarily located in North America, western Europe and Japan. We also sell through third party distributors in China, southern Europe and the rest of the world. Our sales are widely distributed, and no single end-user customer accounted for more than 10% of Protein Platforms' net sales during fiscal 2018, 2017 or 2016.

Protein Platforms Segment Competitors

Our Simple Western platform is a complete replacement for the traditional manual Western blot. As a result, we face competition from the vendors that supply instruments and reagents to traditional Western blot users. These competitors include Bio-Rad Laboratories, GE Healthcare, Merck KGaA, PerkinElmer and Thermo Fisher Scientific. All of these vendors provide elements of the traditional work flow. Similarly, our SimplePlex platform replaces the traditional manual ELISA assay as well as some flow cytometry-based multiplex immunoassays; competitors include those who supply instruments and reagents for ELISAs, including Meso Scale Discovery, PerkinElmer, Thermo Fisher, Luminex, Millipore, Molecular Devices, Tecan BioTek, and Bio-Rad Laboratories. The primary competitors for our Biologics instrumentation are Agilent Technologies, Danaher and PerkinElmer, as well as GE Healthcare, Shimadzu, Thermo Fisher and Waters. We believe our competitive position is strong due to the unique aspects of our products and our product quality.

Protein Platforms Segment Manufacturing

We manufacture our products for this division at various locations in the United States and Canada. We manufacture our own components where we believe it adds significant value, but we rely on suppliers for the manufacture of some of the consumables, components, subassemblies and autosamplers used with, or included in, our systems, which are manufactured to our specifications. We are not dependent on any one supplier and are not required to carry significant amounts of inventory to assure ourselves of a continuous allotment of goods from suppliers. We conduct all final testing and inspection of our products. We have established a quality control program, including a set of standard manufacturing and documentation procedures.

There was no significant backlog of orders for our Protein Platforms products as of the date of this Annual Report on Form 10-K or as of a comparable date for fiscal 2017.

Diagnostics Segment

Diagnostics Segment Products

This segment includes blood chemistry and blood gas quality controls, hematology instrument controls, diagnostic immunoassays, and other bulk and custom reagents for the *in vitro* diagnostic market worldwide. Often we manufacture these reagents on a custom basis to optimize their use in a customer's diagnostic assay. We supply these reagents in various formats including liquid, frozen, or in lyophilized form.

Diagnostics Segment Customers and Distribution Methods

Original Equipment Manufacturer (OEM) agreements represent the largest market for our historical diagnostics products. In fiscal 2018, 2017 and 2016, OEM agreements accounted for $62.8 million, $60.7 million, and $54.2 million, or 57%, 57%, and 52% of division net sales in each fiscal year, respectively. We sell some of our diagnostics products directly to customers and, in Europe and Asia, also through distributors. One OEM customer accounted for approximately 12% of the Diagnostics Division's net sales during fiscal year 2017. This customer did not amount to 10% or more of the Company's consolidated net sales during fiscal year 2017. No customer accounted for more than 10% of the Diagnostics Division’s net sales during fiscal years 2018 or 2016.

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Diagnostics Segment Competitors

We believe we are the third largest supplier of hematology controls in the marketplace behind Beckman Coulter, Inc. and Streck, Inc. For our other control and calibrator products, the principal competitors are Abbott Diagnostics, Beckman Coulter, Inc., Bio-Rad Laboratories, Inc., Siemens Healthcare Diagnostics Inc. and Sysmex Corporation. We compete based primarily on product performance, quality, and price. SeraCare, HyTest Ltd and Thermo Fisher Scientific are additional competitors in the clinical diagnostic manufacturing and reagents markets.

Diagnostics Segment Manufacturing

The primary raw material for our hematology controls products is whole blood. We purchase human blood from commercial blood banks, and porcine and bovine blood from nearby meat processing plants. Although the cost of human blood has increased due to the requirement that it be tested for certain diseases and pathogens prior to use, the higher cost of these materials has not had a material adverse effect on our business thus far. Other controls are derived from various bodily fluids or cells from different animal species, which are then processed in-house to isolate the product of interest or from other bulk reagent suppliers that specialize in certain products. Our other reagent products are manufactured using a variety of suppliers, with no supplier representing a material portion of our business.

Most of the hematology controls products are shipped based on a preset, recurring schedule. However, the majority of our business in this segment are large orders shipped based on our customers' needs; we are highly dependent on our customers’ demand and inventory controls. Consequently, our revenues can vary significantly from quarter to quarter and year to year. There was no significant backlog of orders for our Diagnostics products as of the date of this Annual Report on Form 10-K or as of a comparable date for fiscal 2017.

Geographic Information

Following is financial information relating to geographic areas (in thousands):

	Year Ended June 30,		
	2018	*2017*	*2016*
Net sales:			
United States	$346,293	$313,195	$275,859
EMEA, excluding U.K.	148,599	125,126	103,060
U.K.	33,704	28,401	28,307

APAC, excluding Greater China	48,392	41,463	38,137
Greater China	47,950	39,078	36,199
Rest of world	18,055	15,740	17,461
Total net sales	$642,993	$563,003	$499,023

	Year ended June 30,	
	2018	*2017*
Long-lived assets:		
United States and Canada	$129,360	$119,859
Europe	14,597	14,100
China	1,391	1,165
Total long-lived assets	$145,348	$135,124
Intangible assets:		
United States and Canada	$417,430	$424,579
Europe	21,386	18,710
China	7,516	8,753
Total intangible assets	$446,332	$452,042

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Net sales are attributed to countries based on the location of the customer or distributor. Long-lived assets are comprised of land, buildings and improvements and equipment, net of accumulated depreciation. See the description of risks associated with the Company's foreign subsidiaries in Item 1A of this Annual Report on Form 10-K.

PRODUCTS UNDER DEVELOPMENT

Bio-Techne is engaged in continuous research and development in all of our major product lines. We believe that our future success depends, to a large extent, on our ability to keep pace with changing technologies and market needs.

In fiscal 2018, Bio-Techne introduced approximately 1,500 new products. We also expect to significantly expand our portfolio of products through acquisitions as well as continued product development in our existing businesses. However, there is no assurance that any of the products in the research and development phase can be successfully completed or, if completed, can be successfully introduced into the marketplace.

Year Ended June 30,