PRESSURE BIOSCIENCES INC
Form 10-K
April 16, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

[X] Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 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 001-38185

PRESSURE BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in its Charter)

Massachusetts	**04-2652826**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
14 Norfolk Avenue **South Easton, Massachusetts** (Address of Principal Executive Offices)	**02375** (Zip Code)

(508) 230-1828

(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
None	None

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

(Title of Class)
Common Stock, par value $.01 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

Yes [ ] No [X]

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 [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that registrant was required to submit and post such files.

Yes [X] No [ ]

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, 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 [ ]	Accelerated filer [ ]
Non-accelerated filer [ ]	Smaller reporting company [X]
	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 Exchange Act). Yes [ ] No [X].

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 29, 2018 was $6,045,761 based on the closing price of $3.94 per share of Pressure BioSciences, Inc. common stock as quoted on the OTCQB Marketplace on that date.

As of April 12, 2019, there were 1,699,243 shares of the registrant's common stock outstanding.

Documents Incorporated by Reference

N/A.

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Introductory Comments

Throughout this Annual Report on Form 10-K, the terms “we,” “us,” “our,” “the Company,” “our Company,” and “PBI,” refer Pressure BioSciences, Inc., a Massachusetts corporation, and unless the context indicates otherwise, also includes our wholly-owned subsidiary.

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). In some cases, forward-looking statements are identified by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential” and si expressions intended to identify forward-looking statements. Such statements include, without limitation, statements regarding:

- our need for, and our ability to raise, additional equity or debt financing on acceptable terms, if at all;
- our need to take additional cost reduction measures, cease operations or sell our operating assets, if we are unable to obtain sufficient additional financing;
- our belief that we will have sufficient liquidity to finance normal operations for the foreseeable future;
- the options we may pursue in light of our financial condition;
- the potential applications for Ultra Shear Technology (*UST*);
- the potential applications of the BaroFold high-pressure protein refolding and disaggregation technology
- the amount of cash necessary to operate our business;
- the anticipated uses of grant revenue and the potential for increased grant revenue in future periods;
- our plans and expectations with respect to our continued operations;
- the expected increase in the number of pressure cycling technology (*“PCT”)* and constant pressure (*“CP”*) based units that we believe will be installed and the expected increase in revenues from the sale of consumable products, extended service contracts, and biopharma contract services;
- our belief that PCT has achieved initial market acceptance in the mass spectrometry and other markets;
- the expected development and success of new instrument and consumables product offerings;
- the potential applications for our instrument and consumables product offerings;
- the expected expenses of, and benefits and results from, our research and development efforts;
- the expected benefits and results from our collaboration programs, strategic alliances and joint ventures;
- our expectation of obtaining additional research grants from the government in the future;
- our expectations of the results of our development activities funded by government research grants;

- the potential size of the market for biological sample preparation, biopharma contract services and ultra shear technology;
- general economic conditions;
- the anticipated future financial performance and business operations of our company;
- our reasons for focusing our resources in the market for genomic, proteomic, lipidomic and small molecule sample preparation;
- the importance of mass spectrometry as a laboratory tool;
- the advantages of PCT over other current technologies as a method of biological sample preparation and protein characterization in biomarker discovery, forensics, and histology, as well as for other applications;
- the capabilities and benefits of our PCT Sample Preparation System, consumables and other products;
- our belief that laboratory scientists will achieve results comparable with those reported to date by certain research scientists who have published or presented publicly on PCT and our other products and services;
- our ability to retain our core group of scientific, administrative and sales personnel; and
- our ability to expand our customer base in sample preparation and for other applications of PCT and our other products and services.

These forward-looking statements are only predictions and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements, expressed or implied, by such forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K. Except as otherwise required by law, we expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statement contained in this Annual Report on Form 10-K to reflect any change in our expectations or any change in events, conditions or circumstances on which any of our forward-looking statements are based. Factors that could cause or contribute to differences in our future financial and other results include those discussed in the risk factors set forth in Part I, Item 1A of this Annual Report on Form 10-K as well as those discussed elsewhere in this Annual Report on Form 10-K. We qualify all of our forward-looking statements by these cautionary statements.

ITEM 1. BUSINESS.

Throughout this document we use the following terms: Barocycler®, PULSE®, and BioSeq®, which are registered trademarks of the Company. We also use the terms ProteoSolve™, ProteoSolveLRS™, the Power of PCT™, the PCT Shredder™, HUB440™, HUB880™, micro-Pestle™, PCT-HD™, BaroFold™, Barozyme™ and BaroFlex™ Strips, Ultra Shear Technology, and UST™ all of which are unregistered trademarks of the Company.

Overview

We are focused on solving the challenging problems inherent in biological sample preparation, a crucial laboratory step performed by scientists worldwide working in biological life sciences research. Sample preparation is a term that refers to a wide range of activities that precede most forms of scientific analysis. Sample preparation is often complex, time-consuming and, in our belief, one of the most error-prone steps of scientific research. It is a widely-used laboratory undertaking – the requirements of which drive what we believe is a large and growing worldwide market. We have developed and patented a novel, enabling technology platform that can control the sample preparation process. It is based on harnessing the unique properties of high hydrostatic pressure. This process, which we refer to as Pressure Cycling Technology, or PCT, uses alternating cycles of hydrostatic pressure between ambient and ultra-high levels i.e., 20,000 psi or greater to safely, conveniently and reproducibly control the actions of molecules in biological samples, such as cells and tissues from human, animal, plant and microbial sources.

PCT is an enabling platform technology based on a physical process that had not previously been used to control bio-molecular interactions. PCT uses internally developed instrumentation that is capable of cycling pressure between ambient and ultra-high levels at controlled temperatures and specific time intervals, to rapidly and repeatedly control the interactions of bio-molecules, such as proteins, DNA, RNA, lipids and small molecules. Our laboratory instrument family, the Barocycler®, and our internally developed consumables product line, which include our unique MicroTubes, MicroCaps, MicroPestles, BaroFlex and PULSE® (Pressure Used to Lyse Samples for Extraction) Tubes, and application specific kits (containing consumable products and reagents), together make up our PCT Sample Preparation System (the “PCT SPS”).

In 2015, together with an investment bank, we formed a subsidiary called Pressure BioSciences Europe (“PBI Europe”) in Poland. We have 49% ownership interest with the investment bank retaining 51%. Throughout 2018, PBI Europe did not have any operating activities and we cannot reasonably predict when operations will commence. Therefore, we don’t have control of the subsidiary and did not consolidate them in our financial statements.

Patents

To date, we have been granted 15 United States and foreign patents related to our PCT technology platform, and two additional patents in China related to our Ultra Shear Technology, or UST. We have also received eight patents with our purchase of the assets of BaroFold in December 2017. PCT employs a unique approach that we believe has the potential for broad use in a number of established and emerging life sciences areas, which include, but are not limited to:

- protein characterization
- biological sample preparation – including but not limited to sample extraction, homogenization, and digestion - in such study areas as genomic, proteomic, lipidomic, metabolomic and small molecule;
- pathogen inactivation;
- protein purification;
- control of chemical reactions, particularly enzymatic; and
- immunodiagnostics.

We are also the exclusive distributor, throughout the Americas, for Constant Systems, Ltd,'s ("CS") cell disruption equipment, parts, and consumables. CS, a British company located several hours northwest of London, England, has been providing niche biomedical equipment, related consumable products, and services to a global client base since 1989. CS designs, develops, and manufactures high pressure cell disruption equipment required by life sciences laboratories worldwide, particularly disruption systems for the extraction of proteins. The CS equipment provides a constant and controlled cell disruptive environment, giving the user superior, constant, and reproducible results whatever the application. CS has over 900 units installed in over 40 countries worldwide. The CS cell disruption equipment has proven performance in the extraction of cellular components, such as protein from yeast, bacteria, mammalian cells, and other sample types.

The CS pressure-based cell disruption equipment and our PCT-based instrumentation complement each other in several important ways. While both the CS and our technologies are based on high pressure, each product line has fundamental scientific capabilities that the other does not offer. Our PCT Platform uses certain patented pressure mechanisms to achieve small-scale, molecular level effects. CS's technology uses different, proprietary pressure mechanisms for larger-scale, non-molecular level processing. In a number of routine laboratory applications, such as protein extraction, both effects can be critical to success. Therefore, for protein extraction and a number of other important scientific applications, we believe laboratories will benefit by using the CS and our products, either separately or together.

Primary Fields of Use and Application for PCT

Sample preparation is widely regarded as a significant impediment to research and discovery and sample extraction is generally regarded as one of the key parts of sample preparation. The process of preparing samples for genomic, proteomic, lipidomic, and small molecule studies includes a crucial step called sample extraction or sample disruption. This is the process of extracting biomolecules such as nucleic acid i.e., DNA and/or RNA, as well as proteins, lipids, or small molecules from the plant or animal cells and tissues that are being studied. Our current commercialization efforts are based upon our belief that pressure cycling technology provides a superior solution for sample extraction when compared to other available technologies or procedures and thus might significantly improve the quality of sample preparation, and thus the quality of the test result.

Within the broad field of biological sample preparation, in particular sample extraction, we focus the majority of our PCT and constant pressure ("CP") product development efforts in three specific areas: biomarker discovery (primarily through mass spectrometric analysis), forensics and histology. We believe that our existing PCT and CP-based instrumentation and related consumable products fill an important and growing need in the sample preparation market for the safe, rapid, versatile, reproducible and quality extraction of nucleic acids, proteins, lipids, and small molecules from a wide variety of plant, animal, and microbiological cells and tissues.

Biomarker Discovery - Mass Spectrometry

A biomarker is any substance (e.g., protein, DNA) that can be used as an indicator of the presence, absence or stage of a particular disease-state or condition, and/or to measure or predict the progression and effects of therapy. Biomarkers can help in the diagnosis, prognosis, therapy selection, prevention, surveillance, control, and cure of diseases and medical conditions.

A mass spectrometer is a laboratory instrument used in the analysis of biological samples, often focused on proteins, in life sciences research. It is frequently used to help discover biomarkers. According to the November 2017 published

market report by Markets and Markets “Mass Spectrometry Market by Application (Pharmaceuticals, Biotechnology, Environmental testing), Platform (Single mass spectrometry (Quadrupole, TOF & Ion Trap), Hybrid mass spectrometry (Triple Quadrupole, QTOF & FTMS)) – Global Forecast to 2022, the global mass spectrometry market is expected to grow from USD 3.44 billion in 2016 to USD 5.27 billion by 2022, at a CAGR of 7.4% from 2015 to 2020.

Forensics

The detection of DNA has become a part of the analysis of forensic samples by laboratories and criminal justice agencies worldwide in their efforts to identify the perpetrators of violent crimes and missing persons. Scientists from the University of North Texas and Florida International University have reported improvements in DNA yield from forensic samples (e.g., bone and hair) when using the PCT platform in the sample preparation process. We believe that PCT may be capable of differentially extracting DNA from sperm cells and female epithelial cells captured in swabs collected from rape victims and subsequently stored in rape kits. We also believe that there are many completed rape kits that remain untested for reasons such as cost, time and quality of results. We further believe that the ability to differentially extract DNA from sperm and not epithelial cells could reduce the cost of such testing, while increasing the quality, safety and speed of the testing process.

Histology

The most commonly used technique worldwide for the preservation of cancer and other tissues for long-term storage and subsequent pathology evaluation is to process them into formalin-fixed, paraffin-embedded ("FFPE") samples. We believe that the quality and analysis of FFPE tissues is highly problematic, and that PCT offers significant advantages over current processing methods, including standardization, speed, biomolecule recovery, and safety.

Our customers include researchers at academic laboratories, government agencies, biotechnology companies, pharmaceutical companies and other life science institutions in the United States, Europe, and Asia. Our goal is to continue aggressive market penetration in these target areas. We also believe that there is a significant opportunity to sell and/or lease additional Barocycler® instrumentation to additional laboratories at current customer institutions.

If we are successful in commercializing PCT in applications beyond our current focus area of genomic, proteomic, lipidomic, and small molecule sample preparation, and if we are successful in our attempts to attract additional capital, our potential customer base could expand to include hospitals, reference laboratories, pharmaceutical manufacturing plants and other sites involved in each specific application. If we are successful in forensics, our potential customers could be forensic laboratories, military and other government agencies. If we are successful in histology (extraction of biomolecules from FFPE tissues), our potential customers could be pharmaceutical companies, hospitals, and laboratories focused on drug discovery or correlation of disease states.

Developments

We reported a number of accomplishments in 2018:

On February 14, 2018, the Company announced it had signed a two-year, global co-marketing and distribution agreement with ISS, Inc., a designer and manufacturer of advanced scientific instrumentation.

On May 3, 2018, the Company announced receipt of the first contract utilizing the high-pressure patents and other IP acquired from BaroFold, Inc. in the Company's December 2017 Asset Acquisition. The contract related to evaluating the ability of the acquired PreEMT™ technology platform to enhance the manufacturing process and improve the quality of a specific protein therapeutic drug candidate of the third-party.

On May 15, 2018, the Company announced the conversion of $6.39 million of debt into equity.

On June 12, 2018, the Company announced the conversion of an additional $7.24 million of debt into equity.

On July 12, 2018, The Ohio State University announced the receipt of an $891,000 grant from the USDA to develop – together with PBI – an innovative manufacturing technology to preserve food and beverages using wholesome, recognizable ingredients, no artificial preservatives, and reduced use of heat.

On July 19, 2018, we announced that we were developing a potential breakthrough processing method – based on our patented Ultra Shear Technology, or UST – for high quality, shelf-stable milk and other dairy products that would not require refrigeration or chemical additives.

On August 30, 2018, we announced the award of a key new U.S. patent entitled “Flow-through High Hydrostatic Pressure Microfluidic Sample Preparation Device and Related Methods Therefor.” This new patent (US 9995661) brings the Company’s Intellectual Property (“IP”) estate up to a total of 21 issued patents.

On September 13, 2018, we announced the sale of the first two instruments from our newest line of high-pressure based instrument systems, the HUB880 Explorer.

On September 21, 2018, we announced that our ultra-high-pressure product line of instruments, methods, and technology platforms was prominently featured at the recent Institute of Food Technologists annual meeting in Chicago, IL. The Company’s Ultra Shear Technology platform, particularly its U.S. Department of Agriculture-funded collaborative program with The Ohio State University’s College of Food, Agricultural, and Environmental Sciences, was discussed during the four-day conference.

On October 3, 2018, we announced an acceleration in the development timetable for our novel UST technology platform, in order to pursue commercialization of the technology into major new markets.

On November 7, 2018, Bradford A. Young, Ph.D., MBA joined PBI as Sr. VP and Chief Commercial Officer, where his strong technical and leadership experience is expected to help drive product adoption and help drive revenue growth.

On November 9, 2018, we announced achievement of the first major milestone in the development of our UST technology platform: development of the first working prototype of the UST System.

On November 15, 2018, we achieved the successful development of a proprietary processing method for high quality, water-soluble oils, which we believed had the potential to open up major new opportunities in multiple markets. We said that the initial focus of this new method would be in the CBD oil and cosmetics markets.

On December 18, 2018, the Children's Medical Research Institute in Australia, a major international cancer research center, reported that our patented PCT platform could play a significant role in improving cancer diagnosis and treatment.

Liquidity

Management has developed a plan to continue operations. This plan includes controlling expenses, streamlining operations, and obtaining capital through equity and/or debt financing. We have been successful in raising cash through debt and equity offerings in the past. We have efforts in place to continue to raise cash through debt and equity offerings.

Although we have successfully completed equity financings and reduced expenses in the past, we cannot assure our investors that our plans to address these matters in the future will be successful. Additional financing may not be available to us on a timely basis or on terms acceptable to us, if at all. In the event we are unable to raise sufficient funds on terms acceptable to us, we may be required to:

- severely limit or cease our operations or otherwise reduce planned expenditures and forego other business opportunities, which could harm our business. The accompanying financial statements do not include adjustments that may be required in the event of the disposal of assets or the discontinuation of the business;
- obtain financing with terms that may have the effect of diluting or adversely affecting the holdings or the rights of the holders of our capital stock; or
- obtain funds through arrangements with future collaboration partners or others that may require us to relinquish rights to some or all of our technologies or products.

Corporate Information

We were incorporated in the Commonwealth of Massachusetts in August 1978 as Boston Biomedica, Inc. In September 2004, we completed the sale of Boston Biomedica's core business units and began to focus exclusively on the development and commercialization of the PCT platform. Following this change in business strategy, we changed our legal name from Boston Biomedica, Inc. to Pressure BioSciences, Inc. We began operations as PBI in February 2005, research and development activities in April 2006, early marketing and selling activities of our Barocycler® instruments in late 2007, and active marketing and selling of our PCT-based instrument platform in 2012.

Available Information

Our Internet website address is http://www.pressurebiosciences.com. Through our website, we make available, free of charge, reports we file with the Securities and Exchange Commission ("*SEC*"), which include, but are not limited to, our

annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any and all amendments to such reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. These SEC reports can be also accessed through the investor relations section of our website. The information found on our website is not part of this or any other report we file with or furnish to the SEC.

The SEC maintains an Internet website that contains reports, proxy and information statements and other information regarding Pressure BioSciences and other issuers that file electronically with the SEC. The SEC's Internet website address is http://www.sec.gov.

Sample Preparation for Genomic, Proteomic, Lipidomic and Small Molecule Studies

The Market

Since February 2005, we have focused substantially all of our research and development and commercialization efforts on sample preparation for genomic, proteomic, lipidomic, and small molecule studies. This market is comprised of academic and government research institutions, biotechnology and pharmaceutical companies, and other public and private laboratories that are engaged in studying genomic, proteomic and small molecule material within plant and animal cells and tissues. We elected to initially focus our resources in the market of genomic, proteomic and small molecule sample preparation because we believe it is an area that:

- is a rapidly growing market;
- has a large and immediate need for better technology;
- is comprised mostly of research laboratories, which are subject to minimal governmental regulation;