HEMISPHERX BIOPHARMA INC
Form 424B3
May 02, 2019

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Registration No.s 333-226057 and 333-220756

PROSPECTUS SUPPLEMENT

(To Prospectuses Dated August 3, 2018 and October 12, 2017)

4,550,000 Shares of Common Stock

HEMISPHERX BIOPHARMA, INC.

This Prospectus Supplement should be read in conjunction with the prospectuses dated August 3, 2018 and October 12, 2017, which is to be delivered with this Prospectus Supplement.

We are filing this Prospectus Supplement because we agreed with the holders (the "Holders") of the following Common Stock Purchase Warrants to amend the exercise prices of such Warrants for the purchase of up to an aggregate of 4,550,000 shares of our common stock, par value $0.001 per share (the "Common Stock") as follows:

An aggregate of 1,650,000 Series A Warrants issued April 24, 2018 expiring on October 24, 2020 with a current exercise price of $0.39 per share and an amended exercise price of $0.15 per share (the "2018 A Warrants");

An aggregate of 1,650,000 Series B Warrants issued April 24, 2018 expiring on October 24, 2023 with a current exercise price of $0.39 per share and an amended exercise price of $0.15 per share (the "2018 B Warrants"); and

An aggregate of 1,250,000 Series A Warrants issued August 23, 2017 expiring on March 6, 2022 with a current exercise price of $0.45 per share and an amended exercise price of $0.15 per share (the "2017 Warrants" and, collectively with the 2018 A Warrants and the 2018 B Warrants, the "Warrants").

Our Common Stock is listed on the NYSE American under the symbol “HEB.” The last reported sale price of our Common Stock on the NYSE American on May 1, 2019 was $0.21 per share.

We have retained Maxim Group LLC as our exclusive solicitation agent in connection with the amendment to the exercise prices of the Warrants discussed herein. The solicitation agent has no obligation to arrange for the purchase or sale of any specific number or dollar amount of securities. See “Plan of Distribution” on page S-6 of this prospectus supplement for more information regarding these arrangements.

You should read “Risk Factors” beginning on page S-3 of this prospectus supplement and the risk factors described in other documents incorporated by reference herein before buying our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined whether this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is May 2, 2019.

TABLE OF CONTENTS

Prospectus Supplement

ABOUT THIS PROSPECTUS SUPPLEMENT

On April 24, 2018 and August 23, 2017 we issued the Warrants in private transactions. We registered the shares issuable upon exercise of the 2018 A Warrants and the 2018 B Warrants in a registration statement (Registration No. 333-226057) declared effective on August 3, 2018 and filed the prospectus contained therein (the "2018 Prospectus"). We registered the shares issuable upon exercise of the 2017 Warrants in a registration statement (Registration No. 333-220756) declared effective on October 12, 2017 and filed the prospectus contained therein (the "2017 Prospectus" and, along with the 2018 Prospectus, the "Prospectuses").

The purpose of this Prospectus Supplement is to disclose the amendment of the exercise prices of all of the Warrants to $0.15 per share.

Both this Prospectus Supplement and the accompanying Prospectuses include important information about us, our securities being offered and other information you should know before investing. You should read this Prospectus Supplement and the accompanying Prospectuses as well as additional information described under "Important Information Incorporated by Reference" in this Prospectus Supplement before investing in our securities.

You should rely only on information contained in or incorporated by reference into this Prospectus Supplement and the accompanying Prospectus. We have not, and the solicitation agent has not, authorized anyone to provide you with information that is different. This Prospectus Supplement is not an offer to sell nor is it seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this Prospectus Supplement, the accompanying Prospectus and the documents and information incorporated by reference in this Prospectus Supplement and the accompanying Prospectus are accurate only as of their respective dates, regardless of the time of delivery of this Prospectus Supplement or of any sale of our Common Stock.

Our principal executive offices are located at 2117 SW Highway 484, Ocala, Fla 34473, and our telephone number is (407) 839-0095. We maintain a website at "http://www.hemispherx.net". Information contained on our website is not considered to be a part of, nor incorporated by reference in, this Prospectus. Unless the context otherwise requires, references in this Prospectus Supplement to "Hemispherx," the "Company," "we," "our" or "us" refer to Hemispherx Biopharm Inc. and its subsidiaries on a consolidated basis.

RISK FACTORS

Investment in our Common Stock involves a high degree of risk. In addition to the other information included or incorporated by reference in this Prospectus Supplement and the accompanying Prospectuses, you should carefully consider the risks in the section entitled "Risk Factors" in our Annual Report on Form 10-K for our most recent fiscal year filed with the Securities and Exchange Commission, subsequent Quarterly Reports on Form 10-Q, and in other reports we file with the Securities and Exchange Commission that are incorporated by reference herein, before making an investment decision. The risks are presented as of the date of this Prospectus Supplement and we expect that these will be updated from time to time in our periodic and current reports filed with the Securities and Exchange Commission, which will be incorporated herein by reference. Please refer to these subsequent reports for additional information relating to the risks associated with investing in our Common Stock. The risks and uncertainties described therein could materially adversely affect our business, operating results and financial condition, as well as cause the value of our Common Stock to decline. You may lose all or part of your investment as a result. You should also refer to the other information contained in this Prospectus Supplement and the accompanying Prospectuses, or incorporated by reference, including our financial statements and the notes to those statements, and the information set forth under the caption "Cautionary Statement Regarding Forward-Looking Statements." Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors. Forward-looking statements included in this Prospectus Supplement are based on information available to us on the date hereof, and all forward-looking statements in documents incorporated by reference are based on information available to us as of the date of such documents. We disclaim any intent to update any forward-looking statements. The risks described below and contained in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and in our other periodic reports are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business operations.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Prospectus Supplement and in the accompanying Prospectuses and in the other filings incorporated by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. These statements are based on our management's current beliefs, expectations and assumptions about future events, conditions and results and on information currently available to us.

All statements, other than statements of historical fact, included or incorporated herein regarding our strategy, future operations, financial position, future revenues, projected costs, plans, prospects and objectives are forward-looking statements. Words such as "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate," "think," "may," "could," "wi "should," "continue," "potential," "likely," "opportunity" and similar expressions or variations of such words are intended to identify forward-looking statements but are not the exclusive means of identifying forward-looking statements.

Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to adequately fund our projects as we will need additional funding to proceed with our objectives, the potential therapeutic effect of our products, the possibility of obtaining regulatory approval, our ability to find senior co-development partners with the capital and expertise needed to commercialize our products and to enter into arrangements with them on commercially reasonable terms, our ability to manufacture and sell any products, our ability to enter into arrangements with third party vendors, market acceptance of our products, our ability to earn a profit from sales or licenses of any drugs, our ability to discover new drugs in the future, changing market conditions, changes in laws and regulations affecting our industry, and issues related to our New Brunswick, New Jersey facility. In February 2013, we received a Complete Response Letter from the Food and Drug Administration, or FDA, for our Ampligen New Drug Application, or NDA, for the treatment of CFS. The FDA communicated that we should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analysis. Accordingly, the remaining steps to potentially gain FDA approval of the Ampligen NDA, the final results of these and other ongoing activities could vary materially from our expectations and could adversely affect the chances for approval of the Ampligen NDA. These activities and the ultimate outcomes are subject to a variety of risks and uncertainties, including but not limited to risks that (i) the FDA may ask for additional data, information or studies to be completed or provided; and (ii) the FDA may require additional work related to the commercial manufacturing process to be completed or may, in the course of the inspection of manufacturing facilities, identify issues to be resolved.

In August 2016, we received approval of our NDA from Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica, or ANMAT, for commercial sale of rintatolimod (U.S. tradename: Ampligen®) in the Argentine Republic for the treatment of severe CFS. The product will be marketed by GP Pharm, our commercial partner in Latin America. We believe, but cannot assure, that this approval provides a platform for potential sales in certain countries within the European Union under regulations that support cross-border pharmaceutical sales of licensed drugs. In Europe, approval in a country with a stringent regulatory process in place, such as Argentina, should add further validation for the product as the Early Access Program, or EAP, as discussed below and underway in Europe

in pancreatic cancer. ANMAT approval is only an initial, but important, step in the overall successful commercialization of our product. There are a number of actions that must occur before we could be able to commence commercial sales in Argentina. Commercialization in Argentina will require, among other things, an appropriate reimbursement level, appropriate marketing strategies, completion of manufacturing preparations for launch. Approval of rintatolimod for severe CFS in the Argentine Republic does not in any way suggest that the Ampligen NDA in the United States or any comparable application filed in the European Union or elsewhere will obtain commercial approval.

In May 2016, we entered into a five-year agreement with myTomorrows, a Netherlands based company, for the commencement and management of an EAP in Europe and Turkey related to CFS. Pursuant to the agreement, myTomorrows, as our exclusive service provider and distributor in this territory, is performing EAP activities. In January 2017, the EAP was extended to pancreatic cancer patients beginning in the Netherlands. In February 2018, we signed an amendment to extend the territory to cover Canada to treat pancreatic cancer patients, pending government approval. In March 2018, we signed an amendment to which myTomorrows will be our exclusive service provider for special access activities in Canada for the supply of Ampligen for the treatment of CFS. No assurance can be given that we can sufficiently supply product should we experience an unexpected demand for Ampligen in our clinical studies, the commercial launch in Argentina or pursuant to the EAPs. No assurance can be given that Ampligen will prove effective in the treatment of pancreatic cancer.

Currently, two Ampligen clinical trials are underway with a number of subjects enrolled at university cancer centers testing whether tumor microenvironments can be reprogrammed to increase the effectiveness of cancer immunotherapy, including checkpoint blockade. One is at Roswell Park Comprehensive Cancer Center and the other is at the University of Pittsburgh Medical Center. Two additional studies have been approved for enrollment and subjects are being screened for enrollment recruited at Roswell Park Comprehensive Cancer Center and the University of Pittsburgh Medical Center using Ampligen in conjunction with pembrolizumab. No assurance can be given as to the results of these underway trials. Four additional cancer trials in collaboration with University Medical/Cancer Research Centers using Ampligen plus checkpoint blockade are in various pre-enrollment stages. No assurance can be given as to whether some or all of the planned additional oncology clinical trials will occur and they are subject to many factors including lack of regulatory approval(s), lack of study drug, or a change in priorities at the sponsoring Universities or Cancer Centers. Even if these additional clinical trials are initiated, we cannot assure that these clinical studies or the two studies underway will be successful or yield any useful data.

Our overall objectives include plans to continue seeking approval for commercialization of Ampligen in the United States and abroad as well as seeking to broaden commercial therapeutic indications for Alferon N Injection presently approved in the United States and Argentina. We continue to pursue senior co-development partners with the capital and expertise needed to commercialize our products and to enter into arrangements with them on commercially reasonable terms. Our ability to commercialize our products, widen commercial therapeutic indications of Alferon N Injection and/or capitalize on our collaborations with research laboratories to examine our products are subject to a number of significant risks and uncertainties including, but not limited to our ability to enter into more definitive agreements with some of the research laboratories and others that we are collaborating with, to fund and conduct additional testing and studies, whether or not such testing is successful or requires additional testing and meets the requirements of the FDA and comparable foreign regulatory agencies. We do not know when, if ever, our products will be generally available for commercial sale for any indication.

We outsource certain components of our manufacturing, quality control, marketing and distribution while maintaining control over the entire process through our quality assurance and regulatory groups. We cannot provide any guarantee that the facility or our contract manufacturer will necessarily pass an FDA pre-approval inspection for Alferon manufacture.

The production of new Alferon Active Pharmaceutical Ingredient, or API, inventory will begin once the validation phase is complete. While the facility has already been approved by the FDA under the Biological License Application, or BLA, for Alferon, this status will need to be reaffirmed by a successful Pre-Approval Inspection by the FDA prior to commercial sale of newly produced inventory product. If and when the Company obtains a reaffirmation of FDA BLA status and has begun production of new Alferon API, it will need FDA approval as to the quality and stability of the final product before commercial sales can resume. We will need additional funds to finance the revalidation process in our facility to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection. If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon inventory, our operations most likely will be materially and/or adversely affected. In light of these contingencies, there can be no assurances that the approved Alferon N Injection product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels. In addition, we are currently readying the New Brunswick facility to start manufacturing polymers used for the production of Ampligen to satisfy our future needs. While we anticipate that we will be able to commence manufacturing polymers at the New Brunswick facility, we may need additional funding to continue manufacturing. There cannot be any guarantee that we will obtain adequate funds to sustain manufacturing at the New Brunswick facility or that the facility will be able to manufacture sufficient lots for the commercial launch of Ampligen.

We believe, and are investigating, Ampligen’s potential role in enhancing the activity of influenza vaccines. While certain studies involving rodents, non-human primates (monkeys) and healthy human subjects indicate that Ampligen may enhance the activity of influenza vaccines by conferring increased cross-reactivity or cross-protection, further studies will be required and no assurance can be given that Ampligen will assist in the development of a universal vaccine for influenza or other viruses.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

The information included or incorporated herein also refer to estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

DILUTION

In purchasing shares in this offering, the purchaser's interest will be diluted to the extent of the difference between the exercise price per share and the net tangible book value per share of our Common Stock after this offering. Our net tangible book value as of December 31, 2018 was $4,262,000, or ($0.875) per share of Common Stock. "Net tangible book value" is total assets minus the sum of liabilities and intangible assets. "Net tangible book value per share" is net tangible book value divided by the total number of shares of Common Stock outstanding.

After giving effect to the sale by us of 4,550,000 shares of our Common Stock upon the exercise of all of the Warrants at an exercise price of $0.15 per share, and after deducting the solicitation agent's fees, and $20,000 of estimated offering expenses payable by us, our net tangible book value as of December 31, 2018 would have been approximately $4,877,000 or ($0.916) per share of Common Stock. This amount represents an immediate increase in net tangible book value of $0.0041 per share to existing stockholders and an immediate dilution of $0.0584 per share to the exercising Warrant Holders in this offering.

The following table illustrates the dilution:

Offering price per share		$0.15
Net tangible book value per share as of December 31, 2018	$(0.0875)	
Increase in net tangible book value per share after this offering	$(0.0041)	
Pro forma net tangible book value per share after this offering		(0.916)
Dilution per share to the investor in this offering		$0.0584

The above table is based on 48,734,712 shares outstanding as of December 31, 2018 and excludes, as of that date:

- 107,759 shares of our Common Stock issuable upon exercise of the warrants that may be issued to the solicitation agent in this offering;
- 7,719,612 shares of our Common Stock subject to outstanding options having a weighted average exercise price of $0.35 per share; and
- 9,785,298 shares of our Common Stock that have been reserved for issuance upon exercise of outstanding warrants at a weighted average exercise price of $0.53 per share.

To the extent that any outstanding options or warrants are exercised, new options or shares are issued under our 2018 Equity Incentive Plan, or we otherwise issue additional shares of Common Stock in the future, at a price less than the offering price, there will be further dilution to the investor.

PLAN OF DISTRIBUTION

We engaged Maxim Group LLC ("Maxim" or the "Solicitation Agent") as our exclusive solicitation agent in connection with the amendment of the exercise prices of the Warrants and subsequent exercise by such holders. Maxim is not purchasing or selling any securities, nor is Maxim required to arrange for the purchase and sale of any specific number or dollar amount of securities, other than to use its "reasonable best efforts" to arrange for the sale of securities by us.

For its services in connection herewith, we have agreed to pay to Maxim a cash placement fee equal to 7% of the aggregate proceeds from the exercise of the Warrants and reimburse Maxim for its accountable expenses.

We negotiated the price for the exercise of the Warrants with the Warrantholders. The factors considered in determining the price included the recent market price of our Common Stock, the general condition of the securities market at the time of this offering, the history of, and the prospects, for the industry in which we compete, our past and present operations, and our prospects for future revenues.

The solicitation agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended (the "Securities Act"), and any fees or commissions received by it and any profit realized on the resale of the securities sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As underwriter, the solicitation agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act.

These rules and regulations may limit the timing of purchases and sales of shares of Common Stock by the solicitation agent. Under these rules and regulations, the solicitation agent (i) may not engage in any stabilization activity in connection with our securities and (ii) may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

LEGAL MATTERS

The validity of the issuance of the securities offered hereby have been passed upon by our counsel, Silverman Shin & Byrne PLLC.

EXPERTS

The financial statements as of and for the year ended December 31, 2018 incorporated in this Prospectus Supplement by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2018 have been audited by Morrison, Brown, Argiz & Farra, LLC, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference. The financial statements as of and for the year ended December 31, 2017 incorporated in this Prospectus Supplement by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2017 have been audited by RSM LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference All of such financial statements have been so incorporated in reliance upon the report of such firms given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

This Prospectus Supplement supplements the Prospectuses which are part of registration statements on Form S-1 that we filed with the SEC. This Prospectus Supplement does not contain all of the information included in the registration statements. The registration statements that contain the Prospectuses, including the exhibits to the registration statements, contain additional information about us and the securities offered by this Prospectus Supplement. For further information about us and our securities covered by this Prospectus Supplement and the accompanying Prospectuses, you should refer to the registration statements and the exhibits filed with the registration statements. We are subject to the information requirements of the Securities Exchange Act of 1934 and file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov or through our website at www.hemispherx.net. Information contained on our website is not considered to be a part of, nor incorporated by reference in, this Prospectus.

IMPORTANT INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to "incorporate by reference" the information that we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be an important part of this Prospectus Supplement and the Prospectus, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the following documents and any future filing made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 prior to the termination of the offering:

- Our Annual Report on Form 10-K for the year ended December 31, 2018;
- Our Current Report on Form 8-K, as filed with the SEC on May 2, 2019;
- Our Definitive Proxy Statement on Schedule 14A (other than information furnished) filed with the SEC on April 24, 2019;
- Our Definitive Proxy Statement on Schedule 14A (other than information furnished) filed with the SEC on August 3, 2018;
- A description of our common stock contained in our registration statement on Form S-1, SEC File No. 333-117178, filed on July 6, 2004, and any amendment or report filed for the purpose of updating this description; and
- A description of the Rights to purchase shares of our Series A Junior Participating Preferred Stock, which are attached to all shares of Common Stock, is contained in our registration statement on Form 8-A12B, SEC File No. 0-27072, filed on November 14, 2017.

We are not, however, incorporating by reference any documents or portions thereof, whether specifically listed above or filed in the future, that are not deemed "filed" with the SEC, including our Compensation Committee report or any information furnished pursuant to Items 2.02 or 7.01 of Form 8-K or related exhibits furnished pursuant to Item 9.01 of Form 8-K.

You may request a copy of these filings (other than exhibits, unless they are specifically incorporated by reference in the documents), at no cost, by writing or telephoning us at the following address:

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S-7