



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

DIVISION OF
CORPORATION FINANCE

September 3, 2019

Nathan Robinson
Wilson Sonsini Goodrich & Rosati
900 South Capital of Texas Highway
Las Cimas, Fifth Floor
August, TX 78746-5546

Re: ***SEC v. Barry C. Honig, et al.*, Civil Action No. 1:18-cv-08175 (S.D.N.Y.) (Jan. 10, 2019) -
Waivers of disqualification pursuant to Rule 506(d)(2)(ii) of Regulation D and Rule
262(b)(2) of Regulation A**

Dear Mr. Robinson:

This letter responds to your letter dated August 30, 2019 (“Waiver Letter”), written on behalf of BioCardia, Inc., (“BioCardia”) and constituting an application for waivers of disqualification under Rule 506(d)(2)(ii) of Regulation D and Rule 262(b)(2) of Regulation A under the Securities Act of 1933 (“Securities Act”). In the Waiver Letter, you requested relief from any disqualification that will arise as to BioCardia under Rule 506 of Regulation D and Rule 262 of Regulation A under the Securities Act as a result of the entry of a judgment (“Final Judgment”) on January 10, 2019 in the United States District Court for the Southern District of New York relating to the complaint filed by the Commission on September 7, 2018 against, in relevant part, Dr. Phillip K. Frost and Frost Gamma Investments Trust (together, the “Respondents”).

Based on the facts and representations in the Waiver Letter submitted by BioCardia, and assuming that Respondents comply with the Final Judgment, the Commission has determined that BioCardia has made a showing of good cause under Rule 506(d)(2)(ii) of Regulation D and Rule 262(b)(2) of Regulation A that it is not necessary under the circumstances to deny BioCardia reliance on Rule 506 of Regulation D or Rule 262 of Regulation A by reason of the entry of the Final Judgment. This limited waiver of disqualification applies solely to offerings that are consistent with the conditions and representations set forth in the Waiver Letter dated August 30, 2019. Further, disqualification is not waived as to any offering, including those otherwise meeting the conditions and representations set forth in the Waiver Letter, if Respondents fail to comply with any term of the Final Judgment, or if BioCardia has made any material misrepresentation in its request for a waiver.

For the Commission, by the Division of Corporation Finance, pursuant to delegated authority.

Sincerely,

/s/

Elizabeth M. Murphy
Associate Director
Division of Corporation Finance

August 30, 2019

VIA OVERNIGHT DELIVERY & EMAIL

Elizabeth Murphy, Associate Director
Division of Corporation Finance
Securities and Exchange Commission
100 F Street, N.E.
Washington, DC 20549

Re: BioCardia, Inc. ("BioCardia" or the "Company")

Dear Ms. Murphy:

BioCardia is a clinical-stage company based in San Carlos, California that has developed stem cell therapies for treating cardiovascular disease. The Company's lead therapeutic candidate is in a Phase III pivotal trial. This therapy has shown efficacy in treating ischemic heart failure, a chronic, often fatal disease (50% mortality in five years) that afflicts over five million Americans and for which there is no effective treatment.

BioCardia's ability to complete its clinical trial depends on its ability to raise more money. BioCardia is seeking a waiver under the "bad actor" disqualification provisions in Rule 262 and Rule 506 of the Securities Act of 1933, as amended (the "Securities Act"), to enable the Company to conduct financings in reliance on Regulation A and Regulation D thereunder.

BACKGROUND

Dr. Phillip Frost and Frost Gamma Investments Trust ("FGIT") are beneficial owners of shares of common stock of the Company. They and other defendants were party to a proceeding commenced by the U.S. Securities and Exchange Commission (the "SEC" or "Commission"), *SEC v. Barry C. Honig, et al.*, Civil Action No. 1:18-cv-08175 (S.D.N.Y.) (the "Proceeding"). The Proceeding related to "pump and dump" schemes involving several companies, including two in which Dr. Frost and FGIT invested. Dr. Frost and FGIT have both agreed to settlements with the Commission (the "Settlements") and final judgments were entered on January 10, 2019 against Dr. Frost (the "Frost Final Judgment") and FGIT (the "FGIT Final Judgment" and, together with the Frost Final Judgment, the "Final Judgments"). There were no criminal convictions, and the Company is not aware of any ongoing criminal investigations of Dr. Frost or FGIT arising from the facts stated in the SEC Complaint in the Proceeding (the "Complaint"). As a result of the Final Judgments, the Company is disqualified from making use of exemptions for certain offers made in compliance with Regulation A and Regulation D under the Securities Act pursuant to Rules 262(a)(2) and 506(d)(1)(ii) of the Securities Act.¹

¹ See 17 C.F.R. §§ 230.262 (a) and 230.506(d)(1), respectively.

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Based upon the most recent Schedule 13D filed by Dr. Frost and FGIT, Dr. Frost and FGIT share beneficial ownership of approximately 31.1% of the outstanding common stock of BioCardia, Inc. as of June 30, 2019. All shares of such common stock are directly owned by FGIT and indirectly owned by Dr. Frost as trustee and ultimate beneficiary of FGIT. Dr. Frost and FGIT have no relationship with the Company other than their relationship as beneficial owners of the Company's common stock, except that Dr. Frost is the chairman and chief executive officer of OPKO Health, Inc., which is another shareholder of the Company.

The Proceeding did not involve or in any way relate to the Company, its officers, directors or, except for Dr. Frost and FGIT, any other person or entity covered by the disqualification provisions under Regulation A and Regulation D (each, a "covered person").² However, since Dr. Frost and FGIT beneficially own more than 20% of the outstanding voting securities of the Company, absent a waiver, the Final Judgments prohibit the Company from relying on Rule 262 of Regulation A or Rule 504 or 506 of Regulation D under the Securities Act. On behalf of the Company, we respectfully request that the Commission, pursuant to Rule 262(b)(2) of Regulation A and Rule 506(d)(2)(ii) of Regulation D under the Securities Act, grant a waiver of the disqualification under Regulation A and Regulation D that has arisen for the Company as a result of the Final Judgments.

For the reasons discussed below, we respectfully submit that there is good cause for the Commission to determine that it is not necessary under the circumstances that an exemption from the disqualification provisions under Rules 262(a)(2) and 506(d)(1)(ii) of the Securities Act be denied to the Company.³

The predecessor company (the "Old BioCardia") was founded in 2002 and did business as BioCardia. It was largely funded not by institutions but by individuals who were successful life science entrepreneurs. The company sought to complete a public offering in July 2015 but that offering was withdrawn amid turmoil in the overall financial markets. In October 2016, as an alternative financing strategy, the company completed a reverse merger with an OTC-listed company, Tiger X, that had sold off its prior businesses (the "Merger"). The surviving entity then changed its name to BioCardia, Inc. Dr. Frost and FGIT had been the largest shareholders of Tiger X and thus became large shareholders of BioCardia.

The management team of the Old BioCardia continued as the management team of the Company. The board members of Old BioCardia became members of the Board of Directors of the Company (the "Board") and continue to represent a majority of the Company's Board, which is composed of a total of eight members. The Company's Board also includes the following three Board members that had been

² See 17 C.F.R. §§ 230.262 (a)(2) and 230.506(d)(1)(ii), respectively.

³ *Id.*

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designated by Tiger X: Fernando L. Fernandez, Richard Krasno, Ph.D. and Richard C. Pfenniger, Jr. Two of those three directors, Mssrs. Krasno and Pfenniger, are also independent directors of OPKO Health, Inc., a public company controlled by Dr. Frost, and due to such relationship are influenced, but not controlled by, Dr. Frost and still exercise independent judgment with respect to Company governance matters.

DISCUSSION

The Company has never before sought or needed a Regulation A or Regulation D waiver from the Commission. However, absent the relief requested here, the Final Judgments against Dr. Frost and FGIT would continue to disqualify the Company from undertaking or participating in certain securities offerings otherwise exempt from registration under Regulation A or Regulation D because Dr. Frost and/or FGIT beneficially own 20 percent or more of the Company's outstanding voting equity securities (calculated on the basis of voting power), which disqualifies the Company under Rule 262 for the purposes of relying on Regulation A, or under Rules 504 and 506 for the purposes of relying on Regulation D.⁴

Each of Rule 262(b)(2) under Regulation A and Rule 506(d)(2)(ii) under Regulation D authorizes a waiver of the exemption disqualifications upon a showing of good cause that it is not necessary under the circumstances that the exemption be denied.⁵ In considering whether to grant a waiver, the SEC's Division of Corporation Finance looks to (i) the nature of the violation and whether it involved the offer or sale of securities, (ii) whether the conduct involved a criminal conviction or a scienter-based violation, (iii) who was responsible for the misconduct, (iv) the duration of the misconduct, (v) remedial steps taken and to be taken, and (vi) the impact if the waiver is denied. "No single factor is dispositive"⁶

For the reasons set forth below, we hereby request that the Commission waive the Company's disqualification under Rules 262(a) and 506(d)(1) that has arisen as a result of the Final Judgments.⁷

1. *The Violations Alleged in the Complaint Do Not Involve the Securities of or Conduct of the Company.*

Neither the Complaint nor the Final Judgments giving rise to the disqualifications under Regulation A and Regulation D involve the securities of the Company or any conduct on the part of the Company or any covered person other than Dr. Frost and FGIT. There has been no misconduct on the

⁴ See 17 C.F.R. §§ 230.262 (a) and 230.506(d)(1), respectively.

⁵ 17 C.F.R §§ 230.262 (b)(2) and 230.506(d)(2)(ii), respectively.

⁶ See SEC Division of Corporation Finance, *Waivers of Disqualification under Regulation A and Rules 505 and 506 of Regulation D* (Mar. 13, 2015).

⁷ See 17 C.F.R. §§ 230.262 (a)(2) and 230.506(d)(1)(ii), respectively.

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part of the Company or its management, nor has there been any misconduct by anyone with respect to their holdings in BioCardia of which the Company is aware.

2. *Duration of the Misconduct*

We understand from the Complaint that Dr. Frost's relevant stock-selling activity as stated in the Complaint occurred over a four-day period during October 2013.⁸ The relevant stock-ownership period alleged in the Complaint as the basis for the non-scienter-based injunction⁹ under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), Section 13(d) and the rules thereunder was "from on or about April 2015 to at least on or about December 2015."¹⁰ None of the Company or any covered person other than Dr. Frost and FGIT was involved in any of this activity. In fact, such activity arose before Dr. Frost and FGIT became stockholders in the business of the Company as a result of the Merger in October 2016. To the knowledge of the Company, Dr. Frost and FGIT have not sold any securities of the Company since the Merger in 2016. The Company is only affected by the "bad actor" disqualification provisions of the Securities Act because it entered into the Merger after the events giving rise to the Complaint, before the Complaint was filed, and without knowledge of the events to which the Complaint relates. Therefore, the Company believes the application of the "bad actor" disqualification provisions of the Securities Act to the Company is misdirected and results in unjust consequences to the management, employees and other investors in BioCardia.

3. *Remedial Steps*

As provided in the Final Judgments, Dr. Frost and FGIT are subject to a penny-stock bar that prohibits them, with certain carve-outs, from participating in any offering of penny stock, including engaging in activities with a broker, dealer, or issuer for purposes of issuing, trading, or inducing or attempting to induce the purchase of any penny stock.¹¹ The Final Judgments further provide that Dr. Frost and FGIT may only receive debt securities with no current or future equity conversion feature in connection with any future funding they provide to any issuer whose securities they currently own, which includes the Company.¹²

In addition to these measures taken by the SEC to guard against misconduct, the Company has the following measures in place to guard against misconduct:

⁸ See Complaint, paragraph 83.

⁹ Because the Final Judgments involve only civil, non-scienter-based violations, the "significantly greater" burden to show good cause in criminal or scienter-based cases is not applicable. See SEC Division of Corporation Finance, *Waivers of Disqualification under Regulation A and Rules 505 and 506 of Regulation D* (Mar. 13, 2015).

¹⁰ See Complaint, paragraph 159. The Complaint, paragraph 120, refers also to annual amendments to the 2015 filings, which the Complaint alleges continued to be made incorrectly on an annual basis through January 2018.

¹¹ See Frost Final Judgment, Section IV, page 4; FGIT Final Judgment, Section II, page 2.

¹² See Frost Final Judgment, Section IV(a), page 4; FGIT Final Judgment, Section II(a), page 2.

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- The Company's Code of Business Conduct and Ethics, adopted by the Company's Board and posted on its website, requires its directors, officers and employees to comply with applicable law and to act in an honest and ethical manner, and prohibits such persons from buying or selling securities of the Company based on nonpublic information. The policy also establishes a duty to report violations and has a whistleblower hotline to encourage any misconduct to be reported. This policy is designed to ensure that any misconduct, such as the type involved in the Complaint, will be deterred, detected and remedied.
- Although the Company is not listed on the Nasdaq, the Company has adopted and adheres to the high standards of corporate governance applicable to companies listed on Nasdaq, including that the Company has a majority independent Board and independent Board committees in accordance with Nasdaq rules who act with independent judgment in all corporate governance matters. Because our Board members are independent, they are less likely to be improperly influenced to act in ways that could result in the type of misconduct involved in the Complaint.
- The Company has engaged qualified and respected independent advisors, including its independent auditors, KPMG LLP, who perform annual audits of the Company's financial statements, and legal counsel, Wilson Sonsini Goodrich & Rosati P.C., who has advised the Company in securities and corporate governance matters since 2002. Independent advisors such as these have nationwide reputations for integrity and are highly incentivized to assist and advise their clients to avoid any type of misconduct that could tarnish the reputation of the Company or its advisors.
- The Board has authorized the following representations and warranties:

For the duration of the disqualification period that would apply to the Company in the absence of a waiver:

- a) Dr. Frost and FGIT will not be permitted to participate as investors, advisors or in any other capacity in any capital raising activities by the Company that would be conducted in reliance on Regulation D or Regulation A;
- b) none of Mssrs. Fernandez, Krasno or Pfenniger or any other director designated or nominated by Dr. Frost or FGIT will be permitted to participate as directors, investors, advisors or in any other capacity in any capital raising activities by the Company that would be conducted in reliance on Regulation D or Regulation A; and
- c) Dr. Frost and Mssrs. Fernandez, Krasno and Pfenniger have represented that they will not participate in or otherwise influence any capital raising activities

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conducted in reliance on Regulation D or Regulation A for the duration of the disqualification period that would apply to the Company in the absence of a waiver or take any steps to undermine or subvert the above representations.¹³

- Due to Dr. Frost's relationship to Opko Health, Inc., the Company has terminated, its consulting agreement with Opko Health, Inc. as such agreement provided for, among other things, the assistance of Opko Health, Inc. in fundraising activities of the Company. Such termination evidences the fact that Dr. Frost will not be involved in any capacity with capital raising activities by the Company in reliance on Regulation D or Regulation A for the duration of the disqualification period that would apply to the Company in the absence of a waiver.

The Company believes the foregoing factors are sufficient to ensure that the terms of the Final Judgments with respect to transactions in the Company's securities will be complied with.

4. *Disqualification Would Have a Material Adverse Impact on the Company and Others.*

BioCardia is a small company. It has 27 employees and, as of December 31, 2018, cash assets of \$5.3 million. Most of its resources are dedicated to completion of the Phase III clinical trial. The Company will be incurring net losses at least until its first clinical trial is completed and its cardiac therapy approved for sale. The Company needs to raise additional capital in order to continue its clinical trial and, indeed, continue to operate. The Company is currently organizing to secure additional funding through offerings of equity securities that it needs to consummate prior to the end of July 2019, depending upon whether it may rely upon one or both of Rule 262 of Regulation A and Rule 506 of Regulation D.

The Merger in October 2016 provided sufficient capital to finance the Company's operations through December 2018. In December 2018, the Company conducted a bridge financing of \$4 million in reliance on Regulation D to finance the Company through the first half of 2019. Because of the Company's urgent need for capital at this time, absent an ability to rely on the safe harbors of Regulation A or Regulation D, the Company's options for raising money to support operations beyond July 2019 are limited. Due to the uncertainty surrounding how to conduct an offering in compliance with Section 4(a)(2), many fundraising partners, such as investment banks, won't assist the Company in financings where they can't rely on such safe harbors. In addition, the Company has been advised by investment banks that it will have a greater likelihood of success in a financing if the Company can access a broader base of investors utilizing general solicitation for placements to accredited investors under Rule 506(c) or an offering in reliance on Regulation A.

¹³ The Board further represents that for the duration of the disqualification period that would apply to the Company in the absence of a waiver, in the event Dr. Frost or FGIT designates or nominates any other director, it will receive from those directors the same representation.

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Furthermore, although the Company can conduct an SEC registered public offering to raise money from a broader base of investors through general solicitation, since the Company is not listed on a national securities exchange, it cannot benefit from the provisions of Section 18 of the Securities Act that preempt the application of state securities laws for such an offering. To conduct an SEC registered public offering as an OTCQB listed Company, the Company would be required to incur substantial time and cost to comply with state securities laws, and would be subject to additional uncertainty as to whether such offering would be approved by any particular state in a timely manner or at all. The Company has made an application to list its common stock on a national securities exchange and has filed a registration statement with the SEC (File No. 333-230779) to enable it to conduct a public offering that it hopes to close concurrently with such a listing in order to avoid the time, cost and uncertainty of state securities law compliance for a general solicitation, among other reasons. However, the Company may not qualify for a national securities exchange listing prior to the end of July 2019 when it anticipates requiring additional funding. The Company effected a 9-for-1 reverse stock split on June 6, 2019 and its shares must, among other qualifications, hold a share price of \$3.00 or more on 30 consecutive trading days, making the end of July the earliest the Company could qualify for such a listing and offering. The Company anticipates it may need to conduct a private placement for bridge financing near the end of July 2019 if its offering is unsuccessful or it is unable to qualify for a national securities exchange listing and needs the ability to rely on Regulation D for such private placement. For example, if the planned July 2019 public offering is unsuccessful because of the failure to qualify for a national securities exchange listing but certain investors are still willing to participate in a private placement, the Company may only be able to complete such a private placement in reliance on Rule 506(c) of Regulation D if the placement is deemed to be integrated with the abandoned public offering that utilized general solicitation.

In addition to the Company's immediate funding needs, even if the Company successfully lists on a national securities exchange, it anticipates the need to be able to utilize Regulation D to raise funding on a more expedited basis than is possible for registered public offerings, for example through a PIPE transaction or through utilizing its shares in financing acquisitions or licensing transactions. Without the ability to utilize Regulation D in these circumstances, the Company will be at a competitive disadvantage to competitors that have access to more readily available sources of capital in reliance on Regulation D. In addition, depending upon the circumstances at such time, Regulation D may be the only practical means by which the Company may obtain timely financing. For the foregoing reasons, a Regulation A or Regulation D offering is a more certain and cost effective way for the Company to obtain the financing it needs.

Without the ability to rely on Regulation A and Regulation D, the Company's options for financing are limited and as a result, the Company may be unable to continue to operate beyond the first half of 2019, resulting in the loss of jobs for Company's employees, the loss of millions of dollars for investors, and the delay or cessation of the development of a potentially life-saving therapy for patients

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with certain heart conditions. These are perverse consequences from the “bad actor” disqualification provisions of the Securities Act. The “bad actor” provisions of the Securities Act are intended to minimize harmful consequences from bad actors but in the case of BioCardia are magnifying them.

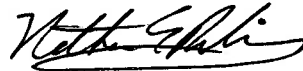
CONCLUSION

For the reasons stated above, we respectfully submit that good cause has been shown that it is not necessary under the circumstances to deny exemptions to the Company. Accordingly, we respectfully request that the Commission (or its Division of Corporation Finance pursuant to delegated authority) waive the disqualifications under Regulation A or Regulation D with regard to the Company resulting from the Final Judgments against Dr. Frost and FGIT.

Please do not hesitate to contact me at (512) 338-5407 if you should have any questions regarding this request.

Sincerely,

WILSON SONSINI GOODRICH & ROSATI
Professional Corporation



Nathan Robinson

Cc: Peter Altman, BioCardia CEO
David McClung, BioCardia CFO
Michael Danaher, Esq.