PUMA BIOTECHNOLOGY, INC.
Form DFAN14A
December 14, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

SCHEDULE 14A

(Rule 14a 101)

INFORMATION REQUIRED IN CONSENT STATEMENT

SCHEDULE 14A INFORMATION

Consent Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant ¨ Filed by a Party other than the Registrant x

Check the appropriate box:

¨ Preliminary Consent Statement

¨ **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**

¨ Definitive Consent Statement

x Definitive Additional Materials

¨ Soliciting Material Under Rule 14a-12

PUMA BIOTECHNOLOGY, INC.

(Name of Registrant as Specified in Its Charter)

FREDRIC N. ESHELMAN, PHARM.D.

JAMES M. DALY

SETH A. RUDNICK, M.D.

KENNETH B. LEE, JR.

(Name of Persons(s) Filing Consent Statement, if Other Than the Registrant)

Payment of Filing Fee (Check the appropriate box):

x No fee required.

¨ Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

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(1) Amount previously paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

FREDRIC N. ESHELMAN

December 11, 2015

Dear Fellow Puma Stockholders:

An Enhanced Board and Improved Oversight is Needed to Achieve Compelling Value Proposition at Puma

I am Fredric N. Eshelman and I beneficially own approximately 1% of the outstanding shares of common stock of Puma Biotechnology, Inc. (Puma or the Company). I invested in Puma because I believe in the value of its asset; however, this value and the potential benefit to patients of successfully bringing neratinib to market can only be realized under proper stewardship, which starts at the board level. Looking ahead, Puma s current board of directors (the Board) would benefit from additional experience in executing on Puma s value proposition.

Therefore, I am seeking your consent to increase the size of Puma s Board from five to nine directors and elect myself and three other highly qualified director nominees James M. Daly, Seth A. Rudnick, M.D. and Kenneth B. Lee, Jr. (the Nominees) as directors of the Company. Having served in management and board roles at a number of successful biotechnology and pharmaceutical companies, the Nominees collectively bring 100 years of relevant industry experience, which includes significant drug development and approval experience.

The Company s arguments as to why you should not support our efforts boil down to the following flawed pillars: (i) five is the optimal board size; (ii) the current Board has the range of experience necessary to guide the Company through the next stages of its development; and (iii) the Nominees would not bring any additive expertise or insight to the Board. These pillars crumble upon further scrutiny of the facts.

I believe that the recent precipitous decline in Puma s stock price, including after the ExteNET results were announced earlier today, is a direct result of the current Board s failure to provide adequate oversight of management, which has led to a lack of transparency with investors and complete mismanagement of market expectations.

Yet, the Company would have you believe the status quo is best for stockholders. Do you agree? Puma s stock price has been whipsawed and you have watched the value of your investment in Puma plummet during the past year. Puma is now at a critical juncture following the recent release of disappointing ExteNET trial results, which sent Puma s stock into a free fall, at one point down 22% following the announcement. The Company s path going forward will be increasingly complex and require more nuanced analysis of strategic options to maximize available opportunities.

You now have the opportunity to ensure that Puma s Board is prepared and capable to successfully address these challenges.

THE COMPANY S CLAIM THAT A FIVE-MEMBER BOARD IS OPTIMAL CONTRADICTS BEST PRACTICES AND INDUSTRY NORMS: NINE IS FINE

While Institutional Shareholder Services (ISS) has described a board of nine to twelve directors as ideal, Puma claims that its current five-member board is optimal. This assertion does not hold up to scrutiny. The Company has admitted that its operations and regulatory filings will become significantly more complex in the near future. The Company will need to develop, and be prepared to execute on, detailed strategies for the commercialization of neratinib in the U.S. and Europe. A larger Board that includes the highly qualified Nominees as directors will provide Puma with the tactical know-how and strategic skills to address these challenges.

In addition, Puma s Board size is hardly consistent with industry practice. The Company disingenuously claims that its Board size is consistent with many other life sciences companies. Despite the Company s attempt at obfuscation, eight of the ten hand-picked peers cited by Puma have boards with more than five directors.

The disconnect between Puma s claims and reality is even more striking when examined alongside peer groups selected by objective third-party sources. Of the peers selected by ISS, Bloomberg and Capital IQ, none have a board with less than six directors; thirteen have nine or more directors on their board.

PUMA S CURRENT BOARD HAS OVERSEEN A PERIOD OF SIGNIFICANT STOCKHOLDER VALUE DESTRUCTION AND LACKS THE RELEVANT INDUSTRY AND PUBLIC COMPANY EXPERIENCE NEEDED TO CREATE VALUE IN THE FUTURE

Puma claims that its current directors possess a well-diversified range of experience necessary to guide the Company through the next stages of its development. A closer look, however, shows that the current Board is underprepared to deal with the near-term challenges and milestones, and would benefit from additional industry, oncological and regulatory knowledge and experience than has been needed since the Company s inception.

The current independent directors have collectively served on the boards of only four public companies other than Puma, one of which went public just within the last year. While Puma claims that the current Board has significant drug development and regulatory experience, this is laughable. In its December 2015 investor presentation (the December Presentation), the Company was unable to list a single drug that its independent directors took through full development. In fact, the most impressive biographical highlights provided in the presentation came from Adrian Senderowicz, who held unspecified positions in the Oncology Drug Division at the FDA.

At this stage in neratinib s development, with a Q1 2016 NDA filing planned, adequate oversight would have ensured that the Company had already begun the drug s commercialization process or initiated discussions regarding potential partnerships. This doesn t appear to be the case, which suggests that the Company plans to rely on M&A to generate stockholder value. This position leaves the Company open to the risk that a deal never materializes, a risk that is exacerbated by the fact that none of the independent directors have significant M&A experience. As a result, the Board is precariously underprepared to evaluate any potential M&A transaction and to weigh execution risks, which could include a lengthy diligence period and the risk that an auction process does not lead to an offer that fully values Puma s business and assets.

This brings us to Puma s CEO & Chairman, Mr. Alan Auerbach, who has been involved in only one significant M&A transaction and has partially developed just a single drug, both of

which occurred during his brief tenure at Cougar. His experience in drug regulatory matters is hardly remarkable, involving just three related prostate cancer products (also arising from Mr. Auerbach s time at Cougar). Other than Puma and Cougar, Mr. Auerbach has served on just one public company board: Radius Health, Inc., a company whose stock price recently fell approximately 11% after it delayed an NDA filing for work health balance, and is down over 34% from its July 2015 peak.

It is clear that the current Board does not have the diversified skills needed to drive value going forward. If there is any doubt, just look at the recent performance of Puma s stock. Under the stewardship of the current Board, Puma s stock has materially underperformed its peer companies and the S&P 500 and NYSE Arca Biotechnology indexes, declining over 48% and 66% during the past six months and one year, respectively, including the stock s almost 6% single-day drop in connection with the ExteNET data presented at the recent San Antonio Breast Cancer Symposium.

In its December Presentation, Puma argues that the performance of its stock since inception compares favorably with that of its peers and the broader indexes. The Company explained the recent decline by noting that development stage companies have increased volatility risk. Volatility alone, however, does not explain the decline in Puma s stock price. The Company s arguments completely ignore the fact that the severe decline realized over the last six and 12 months were caused by the Company s misleading and problematic statements. Management has a history of overpromising, underdelivering and delaying key regulatory milestones. Specific examples are set forth in the presentation I filed with the SEC on November 30, 2015.

Puma claims that it has demonstrated a history of open and active communication with stockholders regarding the progress of drug development. As you are well aware, the reality is that the CEO, Mr. Auerbach, is virtually the only member of Puma s management team communicating with investors and analysts on conference calls.

It is clear that Mr. Auerbach is driving the Puma ship, unencumbered by any sort of meaningful oversight by the independent directors. Given the independent directors lack of experience in the areas most vital to the Board s oversight functions, it is no wonder the Board continues to rubber stamp a failed regulatory and disclosure strategy that has destroyed significant stockholder value.

Effective board oversight and enhanced transparency are critical to maximizing stockholder value. Unless immediate action is taken, I believe the Company s performance will continue to deteriorate and stockholders will be subject to the whims of a management team that is rewarded for soaring stock prices fueled by inflated expectations.

THE HIGHLY QUALIFIED NOMINEES HAVE THE REQUISITE EXPERIENCE AND SKILL SETS NEEDED TO TRANSFORM PUMA

Good corporate governance demands that the Board be forward-thinking and consider director succession planning based on the business needs and strategy over the next several years. Mr. Auerbach recently stated that from a commercial standpoint, there s one of three paths we can take. We can either build out our own commercial infrastructure. We can do some type of a partnership, either worldwide or country-specific or we can sell the entire company.

As neratinib moves into the next phases of drug development, Puma will need to evaluate more complex and nuanced strategic options.

The Nominees bring breadth and depth of experience that will inform their oversight role and allow them to anticipate and address potential risks with various options. The Nominees collectively have served on more than 20 public company boards, more than 20 private company boards, have served as chairman or lead director on 10 private and public company boards, and represent over a century of experience in the biotechnology and pharmaceutical industries.

Here are a just few examples that demonstrate the Nominees additive value. I was the CEO and/or Chairman of two public companies (Pharmaceutical Product Development, Inc. and Furiex Pharmaceuticals, Inc.) that were ultimately acquired for a total of approximately $5 billion. Mr. Lee has served on boards of companies that were sold for a combined value of approximately $7.8 billion. During his tenure at Incyte Corporation, Mr. Daly built a commercial team that achieved significant success, with annual sales increasing from $130 million to $600 million. Dr. Rudnick, a medical oncologist, was responsible for the development and approval of two significant biological compounds used in cancer treatment (alpha interferon and erythopoitetin) at Schering-Plough Corporation, Biogen Inc., and Johnson & Johnson. In his role at Amgen, Mr. Daly oversaw the successful launches of five oncology products.

THE NOMINEES HAVE DEVELOPED A COMPREHENSIVE SET OF BUSINESS INITIATIVES TO TURN PUMA INTO A PROFITABLE AND SUCCESSFUL COMPANY

Whether or not the Company plans to, or is engaged in, M&A discussions, management is responsible for running the Company for its long-term owners. Despite its claims to the contrary, it is not apparent to me that the current Board has a near- or mid-term plan to deal with the disappointing ExteNET results recently announced in San Antonio. Based on the limited public information that Puma has provided to stockholders, the Nominees have discussed and outlined a plan for navigating a path forward with results announced in San Antonio. Key elements include:

Clinical, Regulatory and R&D: The Nominees will propose a complete review of the data from all studies of neratinib, using outside consultants, and have already identified potential issues that the review would need to take into account. This review would greatly clarify the current state of the neratinib data, providing information that would allow the Company to improve its strategies with respect to clinical trials, the regulatory approval process and future R&D.

Commercialization and Marketing: The Nominees have developed a global sales forecast model for neratinib. The model outlines the different possibilities for commercialization of neratinib in various indications based on the strength of future data and regulatory approval. The Nominees plan also addresses the steps that Puma will need to take in order to build a sales, marketing and medical affairs infrastructure for the launch of neratinib. These steps must be taken within the next ten months. There is a right way and a wrong way to launch a product in oncology. Puma only has one shot to get it right.

Manufacturing: The Nominees plan lays out the critical milestones and manufacturing steps that must be undertaken in support of a commercial launch of neratinib. Other issues addressed in the plan include the regulatory pathway for integrating active pharmaceutical ingredient scale up and stability, validation batches, quality control, drug product, analytical methods and qualification of manufacturing equipment.

Finance: The Nominees have analyzed the Company s past approach to raising capital and have developed a forecast of future expenses. The Nominees sales forecast model and estimates of expenses will allow for the development of cash flow models that will facilitate efforts to create the optimal capital structure for the Company going forward.

Business Development: Puma has been the subject of past M&A rumors. There is an immediate need to both review past activities and to determine the potential terms and likelihood of a future transaction in order to better inform the Company s evaluation of its strategic options.

Investor Relations and Communications: Puma has been severely lacking in this area. The Nominees plan sets forth actions the Company can take to improve, which include non-deal road shows, a comprehensive Analysts Day review and making additional members of management available for interaction at conferences, calls, road shows and individual meetings, as well as increased outreach to the financial and medical communities.

Corporate Governance: The Nominees plan sets forth actions to improve oversight and evaluation of the CEO and other senior management personnel in order to ensure that the right people are in the right jobs. In particular, the Nominees plan proposes the separation of the CEO and Chairman roles. The plan also proposes changes to Puma s compensation practices, which are currently excessive, highly dilutive and not in the best interests of stockholders.

I am asking fellow stockholders to take action now to maximize the value of their investment through the proposed board enhancements. The Nominees have a clear vision for maximizing stockholder value and welcome the opportunity to work with fellow board members to execute that vision.

I urge stockholders to sign, date and return the WHITE consent card in the postage-paid envelope previously provided. Please send in your WHITE consent card as soon as possible to ensure that your consent will count.

Thank you for your consideration.

Sincerely,

/s/ Fredric Eshelman

Fredric Eshelman

Additional Information and Certain Disclosures

Dr. Eshelman is the beneficial owner of 300,000 shares of common stock of the Company, representing approximately 1% of the Company s outstanding shares, based upon the 32,435,748 shares of common stock reported by the Company to be outstanding as of November 2, 2015 in its Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the SEC) on November 9, 2015.

Dr. Fredric N. Eshelman, James M. Daly, Dr. Seth A. Rudnick and Kenneth B. Lee, Jr. (collectively, the Participants) have filed a definitive consent statement and accompanying form of consent card with the SEC to be used in the connection with the solicitation of consents (the Consent Solicitation) from the stockholders of Puma to increase the size of the Company s board of directors from five to nine members and elect four new directors. Stockholders of the Company should read the definitive consent statement and other documents related to the Consent Solicitation because they contain important information, including additional information related to the Participants and a description of their director or indirect interests by security holdings. The definitive consent statement and accompanying consent card have been furnished to some or all of the Company s stockholders and are, along with other relevant documents, available at no charge on the internet at www.okapivote.com/pumabiotechnology or on the SEC s website at http://www.sec.gov/. In addition, Okapi Partners LLC, Dr. Eshelman s consent solicitor, will provide copies of the definitive consent statement and accompanying consent card without charge upon request by calling (877) 869-0171 or by emailing info@okapipartners.com.

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