UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): October 15, 2018

REZOLUTE, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	000-54495	**27-3440894**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

1450 Infinite Drive Louisville, CO	80027
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: (303) 222-2128

(Former Address, Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

Our stated strategy has been to build a metabolic focused biopharmaceutical company by in-licensing compelling compounds that we believe clearly target different diseases where there is an unmet need. In December 2017, we completed the latest phase of this strategy by in-licensing RZ358, a fully human monoclonal antibody that is currently in Phase 2 clinical development. RZ358 is being developed to treat congenital hyperinsulinism, a devastating ultra-orphan pediatric disease.

We believe that RZ358 complements our two other metabolic pipeline opportunities including: (i) our plasma kallikrein inhibitor, RZ402, which is a late stage preclinical program that offers the potential of an oral therapy to treat diabetic macular edema, the leading cause of blindness in adults in the US, and (ii) our super-long-acting basal insulin, AB101, which is currently in Phase 1 clinical development to assess the safety and tolerability, pharmacokinetics and
pharmacodynamics of AB101 in patients with diabetes mellitus.

For fiscal and calendar year 2019, we have the following objectives to advance our development strategy: (i) initiate a Phase 2b clinical study for RZ358 in the US and Europe, (ii) complete the necessary toxicology studies for RZ402 to enable the filing of an IND and initiation of clinical studies, and (iii) complete the Phase 1 study for AB101 and explore partnership opportunities. In order to meet these objectives, we need to raise additional capital through an equity financing ("Financing").

Throughout calendar year 2018, we have met with a variety of large and mid-size health care funds ("Funds") to unveil the Rezolute story with RZ358 as our lead pipeline program. Many of these Funds have expressed interest in Rezolute and more than 10 Funds have conducted extensive due diligence on our programs and prospects involving many meetings and hundreds of hours of review and analysis.

By June 2018, it became readily apparent that with few exceptions, Funds were evaluating our prospects based solely upon RZ358. A few Funds did diligence and expressed interest in RZ402; however, given that RZ402 is preclinical, it has generally not been prioritized relative to RZ358. In addition, none of the Funds have expressed any interest in AB101. In fact, there has been universal consensus that we should continue with our AB101 strategy of completing our ongoing Phase 1 study for the program and then seek to out-license the program or terminate it depending upon the Phase 1 study results. Importantly, no Fund has expressed a willingness to provide capital for us to continue to advance AB101 beyond the first study.

Funds have also been clear that they believe that Rezolute needs to raise at least $40 million in order to fund the Company through the completion of our planned Phase 2b study for RZ358. As a result, notwithstanding our initial desire to raise approximately $20-25 million and then conduct additional financings based upon the achievement of clinical milestones, we are now targeting a $40 million raise.

Further, while some Funds either declined to consider an investment in Rezolute or declined to invest following their diligence, by August 2018 various Funds concluded that they would be interested in investing in Rezolute as part of a syndicate on the condition that at least one Fund serve as the lead investor to prepare a term sheet and related documents. In the second half of August 2018, we received a term sheet from one potential investor (the "Lead Investor"); however, we did not believe that the terms were in the best interests of the Company and its shareholders and continued evaluating alternatives.

Another Fund declined to serve as lead investor in Rezolute or to participate in a syndicate as part of the Financing; nonetheless, this Fund suggested that we consider a strategic business combination with one of their existing portfolio companies (the "Portfolio Company"). In the second half of September 2018, we engaged in a diligence process with the Portfolio Company culminating in our receipt of a term sheet proposal from the Portfolio Company for a strategic transaction. Following discussions between the companies on October 11, 2018, we concluded that a transaction with the Portfolio Company was not the best option for Rezolute and its shareholders.

We have continued discussions with the Lead Investor through the first half of October 2018 and have concluded that finalizing a term sheet with that Fund whereby they would invest $7 million in the Financing was the best path forward for the Company—particularly given that other Funds that have completed their diligence have expressed interest in following the Lead Investor as part of a syndicate to raise $40 million.

Our objective is to finalize a non-binding term sheet with the Lead Investor and to then prepare definitive documentation for the Financing while building the syndicate. We believe that it will take several months to complete the Financing particularly if we concurrently up-list onto a national exchange as part of the transaction. In the interim, we will need to secure additional bridge funding given our low cash position.

While no assurance can be given that: (i) we will execute a term sheet with the Lead Investor; (ii) we will be able to negotiate a purchase agreement that is satisfactory to all parties; (iii) we will be able to generate enough interest from other Funds to raise the full $40 million; (iv) that we will be able to raise additional bridge financing to continue operations pending the completion of the Financing, we believe that this Financing strategy is the best option for the Company and its shareholders. Our inability to either secure additional bridge funding or complete the Financing would materially and adversely impact our ability to continue as a going concern.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REZOLUTE, INC.

Date: October 15, 2018

By: /s/ Nevan Elam
Name: Nevan Elam
Title: Chief Executive Officer