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): August 12, 2019

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

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

201 Redwood Shores Pkwy, Suite 315, Redwood City, CA 94065
(Address of Principal Executive Offices, and Zip Code)

650-206-4507
Registrant's Telephone Number, Including Area Code

Not Applicable
(Former Name or Former Address, if 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 (*see* General Instruction A.2. below):

☐ Written communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
N/A	**N/A**	**N/A**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2 of this chapter).

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. ☐

Item 1.01 Entry into a Material Definitive Agreement.

On August 12, 2019, we entered into a Stock Purchase Agreement with an accredited investor whereby we issued an aggregate of 13,103,448 shares of common stock (the "**Offering Shares**") at a price per Offering Share of $0.29. The sale and issuance of the Offering Shares was in connection with the closing of the second tranche of our previously announced common stock offering (the "**Offering**") for aggregate gross proceeds to the Company of approximately $23.7 million (the "**Offering**"). The sale and issuance of the Offering Shares have been determined to be exempt from registration under the Securities Act of 1933, as amended (the "**Securities Act**") in reliance on Section 4(a)(2) thereof and Rule 506 of Regulation D promulgated thereunder as a transaction by an issuer not involving a public offering, in which the investors are accredited and have acquired the securities for investment purposes only and not with a view to or for sale in connection with any distribution thereof. Such Offering Shares may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

Canaccord Genuity LLC and JMP Securities LLC (each, an "**Agent**" and together, the "**Agents**") acted as co-lead agents for the Offering pursuant to a letter agreement between the Company and the Agents dated June 12, 2019 (the "**Letter Agreement**"). In accordance with the Letter Agreement, the Agents are entitled to receive a cash fee equal to 6% of the gross proceeds of the Offering (each Agent receiving a 3% of such gross proceeds).

We agreed to use our commercially reasonable efforts to prepare and file with the SEC within sixty (60) calendar days after the closing of the Offering a registration statement under the U.S. Securities Act of 1933, as amended (the "**Registration Statement**"), to permit the resale of the Offering Shares purchased in the Offering. We also agreed to use our commercially reasonable efforts to cause the Registration Statement to be declared effective within ninety (90) calendar days following the closing of the Series AA Financing.

RULE 135C NOTICE

We are providing this Current Report on Form 8-K in accordance with Rule 135c under the Securities Act of 1933, as amended, and the notice contained herein does not constitute an offer to sell the Company's securities, and is not a solicitation for an offer to purchase the Company's securities. Any securities that may be offered pursuant to any agreement related to the Offering have not been registered under the Securities Act of 1933, as amended, and may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements.

Item 3.02 Unregistered Sales of Equity Securities.

The information disclosed in Item 1.01 of this Current Report on Form 8-K is incorporated by reference into this Item 3.02.

Item 7.01 Regulation FD Disclosure.

On August 8, 2019, at the Company's CEO spoke at the Canaccord Genuity's 39th Annual Growth Conference. A transcript of the CEO's remarks is attached hereto as Exhibit 99.1. The information in this Item 7.01 and Exhibit 99.1 is being furnished and is not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits. The following Exhibits are furnished as part of this Current Report on Form 8-K.

Exhibit No.	**Description**
10.1	Form Purchase Agreement for Shares of Common Stock (previously filed with our current report on Form 8-K filed with the SEC on July 30, 2019 and incorporated herein by reference)
99.1	Presentation Transcript

*being furnished and is not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section.

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: August 13, 2019

By: */s/ Keith Vendola*
Keith Vendola
Chief Financial Officer

Exhibit Index

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Company Name: Rezolute, Inc. (RZLT)
Event: Canaccord Genuity's 39th Annual Growth Conference
Date: August 8, 2019

<<Michelle Gilson, Analyst, Canaccord Genuity>>

Hi, good morning. Thank you so much for joining us and for those of you who just stepped into the room. My name is Michelle Gilson. I am one of the biotech analysts here at Canaccord Genuity. It's my pleasure to introduce Nevan Elam, the CEO of Rezolute. Rezolute is an orphan and rare disease endocrinology company with very exciting year ahead. So we're excited to hear more from Nevan.

<<Nevan Charles Elam, Chief Executive Officer>>

Thank you very much. Good morning, everyone. Thank you for taking the time to join us. Happy to be here and appreciate the opportunity to share the Rezolute story with you. We are a development stage company in the clinic and we are focused on treating diseases that are really related to the unwanted changes within the metabolic system. And the reason why I say unwanted changes within the metabolic system, the metabolic system itself is really characterized and defined by constant series of change.

Change is fundamental at the biochemical level, 24 hours a day, complicated pathways and signaling from sleep through nighttime, from infancy all the way through adolescence into adulthood. Change is constant and important and most of those changes are positive. It's part of how we function. And perhaps the backbone of the changes that really define us are the change that's very basic. Something we all like doing. I think some of us maybe do it too much and that's eating.

Eating is very central to the metabolic functioning of the body. And it's one of the necessary changes that actually allows us to live of course. Here food itself is not really something that is energy. Those are complex molecules that need to be broken down and we do that through the catabolic process as we break down those molecules into simple molecules that allow us to digest and to convert that into energy to be either used immediately or stored for later use very elegant system.

And the metabolic system as we think about it at Rezolute really is defined by contrast or changes that are driven by a symbiotic process between opposing forces. Often we see opposing forces in nature and our metabolic system is no different where the goal is to achieve balance or homeostasis. Think for example between the relationship of insulin and glucagon two hormones that are implicated in the processing and management of our blood glucose levels in response to the food that we eat and carbohydrates that are converted into sugars, insulin is secreted by the pancreas allowing the cells throughout our body to uptake that glucose and otherwise have the glucose converted into glycogen to be stored in the liver or in muscle for future use.

In response to lack of food or perhaps extensive exercise, we see the release of glucagon as an opposing hormone, which stimulates the liver in response to release glycogen for energy for our use. That symbiotic yin and the yang relationship between opposing forces, all with the goal of creating balance.

That's nice. But as we all know, life is not perfect and things are not always in balance. And the imperfections that do occur or the unwanted changes occur as well within the metabolic system. Think for example, of an autoimmune deficiency or perhaps, a lifestyle predicated upon eating way too much unhealthy food, a lack of exercise, extensive periods of time with elevated blood glucose levels and the result is the pandemic of diabetes an unwelcome change, or consider, for example, a side effect of diabetes as an unwelcome change.

As a result of the narrowing of blood vessels through extensive periods of time of elevated blood glucose, we experience side effects that are complicated such as hypertension, potential stroke and amputation as a side effect of diabetes or considered genetic defects that may result in a problem and unwanted change when they're almost signaling pathways in the metabolic process actually breaks down and the result is internally chaos in different disease states. All of this within the metabolic system relates and translates into a high unmet need and we are driven at Rezolute and our focus is purely in the metabolic space to bring therapies forward that we think can make a difference in some of these disease states.

I'm going to spend a bulk of my time on our lead program, which is RZ358. It's an ultra-orphan indication for a genetic disorder known as congenital hyperinsulinism. But before I get to that, I will make a couple of comments about our company, as well as touch on the other two programs in our pipeline. Our strategy has been to build this company not as a research organization, but to really do it as a development organization focused on clinical candidates and to bring those forward. As a result, we are an asset role up strategy rather than internal development. And again, not looking at research but using our expertise within endocrinology and metabolic disease to bring forward drug candidates that we think are worthy based on our diligence and our understanding of the metabolic pathways to put forward into early clinical development with the goal of course, bringing a drug forward that's eventually approved.

Starting at the bottom here of our pipeline and let me just touch on AB101 briefly. That is the program that we began the company with. It is a super long-acting basal insulin to treat diabetes. There's been a whole host of things that have happened in the last four years within diabetes and basal insulin in particular and principally approximately 20 years ago with the introduction of Lantus, we had the first daily insulin by injection. And in those last 20 years, a lot of the pharmaceutical companies including Rezolute, have looked to see whether we can extend the treatment paradigm to weekly dosing.

Most of those efforts that have been undertaken are analogs of insulin, and very complicated formulations. We do something very different. We take human insulin, we encapsulate it in a microsphere and inject it. What we've seen pharmacologically in the diabetic minipig models as well as in the dog is a slow, steady release of insulin corresponding with glucose control. That program is now in Phase 1, although it's a Phase 1 that's a little unusual because we are actually doing this in Southern California in the euglycemic clamp study in patients that have type 1

diabetes. So we actually titrate them off of Lantus and then inject them with our formulation looking at both pharmacokinetics as well as pharmacodynamics. That study will read out this year.

And our strategy with AB101 is very binary. You say the word diabetes, you say the word insulin and the world automatically thinks big pharma, Rezolute is not big pharma. We are a small development organization. The goal is to have proof-of-concept. Hopefully we'll achieve proof-of-concept with that study and then we'll look to out license the program. And if the study doesn't meet the endpoints that we expect, then we won't develop it any further.

Moving up from AB101, you'll see RZ402, a program we're very, very excited about. And this is looking at an unwanted change in diabetes, side effect of diabetes, diabetic macular edema, which is a massive problem. The leading cause of blindness in most of the world, it starts off with vision blurriness and blind spots and eventually leads to blindness of swelling of the macula. Today the standard of care to treat diabetic macular edema is through anti-VEGF intravitreal injections. So injections into the eye, not the most ideal route of administration has led to a whole host of compliance issues as we've learned, naturally patients don't like taking an injection into the eye and physicians don't necessarily like giving them.

What we have is for our diabetic macular edema is the alternative pathway to VEGF and this is the kallikrein pathway. We have plasma kallikrein inhibitor, which we've seen in our animal models inhibiting vascular leakage significantly up to 90% primate as well as in the dog, in a very exciting program because this is oral. Now when you think of an eye disease, you typically think of something that's actually in the eye. But this is not the classic eye disease. This is vascular leakage because of leaky blood vessels as a result of diabetes at the retinal interface, there's leakage into the eye. So it's about inhibiting or preventing that leakage rather than actually thinking of it as a true classic eye disease. We are finishing up our toxicology now and are looking forward to filing an IND middle of next year and getting this program into the clinic and to bring forward what we hope would be a great treatment option in this space.

Congenital hyperinsulinism, I'll now spend a few minutes and talk about our lead program RZ358. Congenital hyperinsulinism again is a genetic disorder caused by one of 11 different genetic mutations. It is a very serious disease because it is the exact opposite of diabetes. It is the release of insulin regardless of blood glucose levels. Insulin is freely released creating a state where in this case, children are hypoglycemic, which can lead to brain injury and ultimately potentially death if not treated. It's a rare disease in about one in 50,000 live births. It can be one in 30,000 in some regions and as high as one in 2,500 live births in regions such as portions of the Middle East where you have high rates of consanguinity.

The disease itself is characterized by a constant fear on behalf of patients and their families, fear of hypoglycemia and what can happen, and constant monitoring. Here behind me, you can see pictures of three children that actually have the disease. And you can imagine for those of you that have children what it would feel like to be a new parent and to live in a state where not you adjusting to all of the issues associated with raising children and dealing with an infant, trying to figure out why the infant is crying, why it's upset, but now in this case you're obsessed with make sure the infant has nutrients constantly, 24 hours a day to prevent hypoglycemia.

Turns out that that fear is a real fear because what we do know is about 30% to 50% of the children and those who then become adults actually have neurological impairment some form or another. Meaning they've experienced hypoglycemia significant enough in episodes that have led to hypoglycemic state, that has led to an impairment neurologically.

What we also know is that there was an observational study that was done and the observational study we took a look at patients that are actually on standard-of-care and discovered that on average patients, three hours a day are in a hypoglycemic state. So what can be done about this disease? There are no approved therapies today, not one. Everything that's used is used essentially off label. The first order of business is recognizing that the infant is in a hyperglycemic state, usually presenting within the first month of life, perhaps definitely within the first year.

Once that is actually recognized, the first treatment option is a drug known as diazoxide. Diazoxide is an old drug, it was approved in the 1970s as a vasodilator. The drug itself actually is very useful in so far as it does stop insulin production. And that drug works in about 50% of the patients that actually does stop their insulin production. Unfortunately, it does come with some side effects. Side effects range from those that are visual like hypertrichosis or extensive hair growth, mostly noticeable on the brow or in the extremities of the children, particularly difficult issue for young, pre-adolescent females, as they go through the growing stages.

But there are also other issues associated with use of diazoxide. There is a black box warning the pulmonary hypertension that was issued by the FDA in 2015. And there are other side effects like fluid retention, recording diuretics, and other issues. But it does work in 50% of the patients, not the best drug, but at least it does stop the insulin production. For the rest of the patients there's a cocktail approach that's used to try to figure out what's best to treat each one of these children, long-acting somatostatin analogues are used. They're useful again blunting or stopping insulin production, tube feeds are used, all again with the hope of making sure that hypoglycemia is actually a state that can be avoided.

With long-acting somatostatin analogues there is tachyphylaxis. So that is an issue as well. So what you find is those pediatric endocrinologists that actually treat the disease really are constantly looking into their bag of tricks to try to manage the disease as best as possible. But there is no doubt, there is a high unmet need and that is the unmet need that we're tackling with our drug, RZ358.

RZ358 is a very interesting drug for us because it is a fully human monoclonal antibody. Unlike the other therapies that we've just discussed, this has been designed to treat congenital hyperinsulinism on point. Furthermore, the other therapies look to try to blunt insulin production. RZ358 actually works downstream, meaning we are agnostic to any of the genetic mutations that occur because we're actually looking at the target cells throughout the body systemically, looking to reduce the signaling in the allosteric fashion, which I'll talk a little bit more about in a minute to really, if you think about it, dim the signal, the insulin signal dose dependently and to be able to then avoid hypoglycemia.

We've seen the pharmacological profile extensively first off in the mouse model where we noticed that it we were able to successfully correct hypoglycemia. We then moved into a Phase 1 study, healthy volunteers, did a insulin tolerance test. And again, the same mechanism of action was very effective at returning back to normal from a hypoglycemic state through the administration of RZ358 and now of course looking at later development.

The mechanism of action of RZ358 again being a fully human monoclonal antibody is the binding to an allosteric site. So insulin still binds the target cells and it binds in this normal fashion. But with RZ358 binding, at a different site, it actually is able to reduce the signaling. And that effectively is the key and it's reversible. So it's dose dependent. And what's really interesting about the drug is that it only operates in the presence of elevated insulin levels. So insulin levels are low, RZ358 is not active in tripling that reduction and signaling. So bi-directionally it actually operates, which we think is very elegant as an approach.

Beyond the Phase 1 study, we have completed a Phase 2 study which was very interesting as the first proof-of-concept into looking at congenital hyperinsulinism patients, where we went into patients and dosed them. The drug is administered intravenously. It's about a 30-minute infusion. And based on the profile, what we've seen with the half life of 21 days we would expect this to be administered biweekly. In this Phase 2a study, most interesting thing is that clinically if you think about what's significant in terms of reducing hypoglycemia, it's about 20% reduction in episodes, as well as the duration of those episodes. So if you can reduce it by about 20%, it is of significance. What we notice in the very severe patients with disease up to 70% reduction in hypoglycemia into incidence rate. And that's what's given us the most confidence now to move forward into later stage development, which is what we're poised to do this year.

We are moving into our Phase 2b study, which will commence this year. Protocols are approved in Europe as well as in the U.S. We have our CRO fully engaged. What's nice about working in orphan diseases, I've done so for many years is that the tight network. So, the family advocacy group, Congenital Hyperinsulinism International we work closely with a wonderful organization, as well as with the KOLs themselves, both in the U.S., as well as in Europe. And there's motivation amongst the parents and families. And when we meet them at the family conferences because this is the promise potentially this being a Phase 2b study, then looking at potentially Phase 3 of getting closer to approval where finally there'd be a drug would be available to their children.

The Phase 2b study that we'll be doing is open-label, which is very useful because we'll be able to interact freely with the regulatory authorities, which as you know, is very common in the orphan space. Being able to make decisions about how we bring this forward, looking at different dosing regimens. So we're going from 3 mg/kg up to 12 mg/kg, over a course of eight weeks. And you know again what is not atypical in the orphan space, each patient will act as it's his or her own baseline. So there's a long screening period, we measure them on a continuous glucose monitor over the course of about 10 days and determine the number of episodes they're having and the duration of those episodes. Our goal in this study where glucose is truly the biomarker is to demonstrate that a reduction on average of number of episodes of hypoglycemia and the duration of those episodes.

We look forward to getting into the first dosing again in the next few months coming up and the study itself will be about a year long and then look forward to reporting more as we move forward there.

Some of the key highlights, I think, just to bring this to closure. Of course, the RZ358 program as an ultra-orphan program is our lead program, drives a lot of interest from the investment community, given in the pediatric space and the pediatric voucher that comes with it and the chance to actually be potential first-in-class, as well as the best-in-class drug. And that's what has us very excited to bring that forward.

And then with RZ402 in the ophthalmological space, potentially shifting the treatment paradigm away from intravitreal injections to an oral would be tremendous looking at the kallikrein pathway. So we look forward to getting that into the clinic next year. Now I think a lot of the interest is muted because we're not in the clinic yet. But as we are closer to getting into the clinic, I expect to be talking a lot more about RZ402.

And finally AB101, I'm looking forward to completing that study this year with our super-long-acting basal insulin and again hopefully achieving a result that's positive from the pharmacokinetic and pharmacodynamic perspective and out licensing that program and moving the company forward.

One of the unwanted changes that happens is a change that we want to move to a positive is moving from an OTC company, because we are currently publicly listed over-the-counter, which has been an odyssey to migrating onto a national exchange, something that we will be doing this year. We've been fortunate to secure substantial investment of around $50 million this year into the company. That injection of capital is allowing us to push these programs forward as aggressively and as swiftly as possible.

And with that, I would like to thank you for taking the time and appreciate your attention.